



# Dasa-Rägister

**IQ-0218-01**

Certificato n.  
Certificate n.

**2018-02-06**

Data di prima emissione  
First issue date

**2024-02-05**

Data di ultima emissione  
Last issue date

**2027-02-05**

Data di scadenza  
Expiry date

C.E.O.

Dasa-Rägister S.p.A.  
Italy – 00071 Pomezia – Roma  
Via dei Castelli Romani, 22  
Tel. +39-0691622002  
Fax +39-069107126  
www.dasa-raegister.com



SGQ N° 052A

Membro degli Accordi di Mutuo Riconoscimento  
EA, IAF e ILAC  
Signatory of EA, IAF and ILAC  
Mutual Recognition Agreements

## Dasa-Rägister S.p.A.

certifica che il sistema di gestione per la qualità di  
certifies that the quality management system of

# S.M.I. MEDICAL S.r.l.

Italia - 54033 - Carrara (MS) - Via Rinchiosa, 20/C - Frazione Marina - Sede  
Legale

è' stato verificato e trovato conforme ai requisiti dello standard  
has been assessed and found in compliance with the standard requirements

## UNI EN ISO 9001:2015

per il sito  
for the site

Italia - 56035 - Casciana Terme Lari (PI) - Via Piemonte, 112

per le seguenti attività aventi come oggetto  
**Progettazione, produzione, commercializzazione, assistenza tecnica e validazione di sterilizzatrici a vapore, di macchine di lavaggio e disinfezione di strumentario chirurgico e di macchine di lavaggio e sterilizzazione di strumenti endoscopici**

for the following activities having as object  
**Design, production, commercialization, technical assistance and validation of steam sterilizers of surgical instrument cleaning and disinfection machines, endoscopic instruments cleaning and sterilization machines**

Settore/i - Sector/s **19 29**

Informazioni puntuali e aggiornate circa lo stato della presente Certificazione sono disponibili all'indirizzo [www.dasa-raegister.com](http://www.dasa-raegister.com)  
Punctual and updated information regarding this Certification is available at [www.dasa-raegister.com](http://www.dasa-raegister.com)

Riferirsi alla documentazione del Sistema di Gestione Qualità dell'Organizzazione per i dettagli delle singole esclusioni ai requisiti della Norma UNI EN ISO 9001:2015.  
La validità del presente Certificato è subordinata al rispetto delle prescrizioni del Regolamento di Certificazione Dasa-Rägister, dei requisiti della Norma UNI EN ISO 9001:2015, ad un programma di sorveglianza annuale e ad un riesame ogni tre anni.

Refer to the Documents of the Quality Management System of the Organization for details regarding the exclusions to UNI EN ISO 9001:2015 Standard requirements.  
The validity of this Certificate is subordinated to a full respect of that prescribed in Dasa-Rägister's Certification Regulation, of UNI EN ISO 9001:2015 Standard requirements, to an annual surveillance programme and to a three yearly re-assessment.



# Dasa-Rägister

**IS-0324-01**

Certificato n.  
Certificate n.

**2024-03-01**

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**2024-03-01**

Data di ultima emissione  
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**2027-02-28**

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C.E.O.

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SCR N° 016F

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## Dasa-Rägister S.p.A.

certifica che il sistema di gestione per la sicurezza di  
certifies that the safety management system of

# S.M.I. MEDICAL S.r.l.

Italia - 56035 - Casciana Terme Lari (PI) - Via Piemonte, 112

è stato verificato e trovato conforme ai requisiti dello standard  
has been assessed and found in compliance with the standard requirements

## UNI ISO 45001:2023

per le seguenti attività aventi come oggetto  
**Progettazione, produzione, commercializzazione, assistenza tecnica e validazione di sterilizzatrici a vapore, di macchine di lavaggio e disinfezione di strumentario chirurgico e di macchine di lavaggio e sterilizzazione di strumenti endoscopici**

for the following activities having as object  
**Design, production, commercialization, technical assistance and validation of steam sterilizers of surgical instrument cleaning and disinfection machines, endoscopic instruments cleaning and sterilization machines**

Settore/i - Sector/s **29 19**

Informazioni puntuali e aggiornate circa lo stato della presente Certificazione sono disponibili all'indirizzo [www.dasa-raegister.com](http://www.dasa-raegister.com).  
Punctual and updated information regarding this Certification is available at [www.dasa-raegister.com](http://www.dasa-raegister.com).

La validità del presente Certificato è subordinata al rispetto delle prescrizioni del Regolamento di Certificazione Dasa-Rägister, dei requisiti della Norma UNI ISO 45001:2023, ad un programma di sorveglianza annuale e ad un riesame ogni tre anni.

The validity of this Certificate is subordinated by a full respect of that prescribed in Dasa-Rägister's Certification Regulation, of UNI ISO 45001:2023 Standard requirements, to an annual surveillance programme and to a three yearly re-assessment.



# Dasa-Rägister

**IE-0221-01**

Certificato n.  
Certificate n.

**2021-02-01**

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**2024-01-26**

Data di ultima emissione  
Last issue date

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Expiry date

C.E.O.

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SGA N° 0300

Membro degli Accordi di Mutuo Riconoscimento  
EA, IAF e ILAC  
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Mutual Recognition Agreements

## Dasa-Rägister S.p.A.

certifica che il sistema di gestione per l'ambiente di  
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Italia - 56035 - Casciana Terme Lari (PI) - Via Piemonte, 112

è stato verificato e trovato conforme ai requisiti dello standard  
has been assessed and found in compliance with the standard requirements

## UNI EN ISO 14001:2015

per le seguenti attività aventi come oggetto

**Progettazione, produzione, commercializzazione, assistenza tecnica e validazione di sterilizzatrici a vapore, di macchine di lavaggio e disinfezione di strumentario chirurgico e di macchine di lavaggio e sterilizzazione di strumenti endoscopici**

for the following activities having as object

**Design, production, commercialization, technical assistance and validation of steam sterilizers, of surgical instrument cleaning and disinfection machines, endoscopic instruments cleaning and sterilization machines**

Settore/i - Sector/s **19 29**

Informazioni puntuali e aggiornate circa lo stato della presente Certificazione sono disponibili all'indirizzo [www.dasa-raegister.com](http://www.dasa-raegister.com).  
Punctual and updated information regarding this Certification is available at [www.dasa-raegister.com](http://www.dasa-raegister.com).  
Certificazione rilasciata in conformità al Regolamento Tecnico ACCREDIA RT - 09.  
Certification issued in compliance with Technical Regulation ACCREDIA RT - 09.

La validità del presente Certificato è subordinata al rispetto delle prescrizioni del Regolamento di Certificazione Dasa-Rägister, dei requisiti della Norma UNI EN ISO 14001:2015, ad un programma di sorveglianza annuale e ad un riesame ogni tre anni.

The validity of this Certificate is subordinated by a full respect of that prescribed in Dasa-Rägister's Certification Regulation, of UNI EN ISO 14001:2015 Standard requirements, to an annual surveillance programme and to a three yearly re-assessment.



# Dasa-Rägister

**IMD-0218-01A**

Certificato n.  
Certificate n.

**2018-02-06**

Data di prima emissione  
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## Dasa-Rägister S.p.A.

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certifies that the quality management system of

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Italia - 54033 - Carrara (MS) - Via Rinchiosa, 20/C - Frazione Marina - Sede  
Legale

è stato verificato e trovato conforme ai requisiti dello standard  
has been assessed and found in compliance with the standard requirements

## UNI CEI EN ISO 13485:2021

per il sito  
for the site

Italia - 56035 - Casciana Terme Lari (PI) - Via Piemonte, 112

per le seguenti attività aventi come oggetto

**Commercializzazione e assistenza tecnica di sterilizzatrici a vapore, a perossido di idrogeno, di macchine di lavaggio e disinfezione di strumentario chirurgico e di macchine di lavaggio e sterilizzazione di strumenti endoscopici**

for the following activities having as object

**Commercialization and technical assistance of steam sterilizers, hydrogen peroxide sterilizers, of surgical instrument cleaning and disinfection machines, endoscopic instruments cleaning and sterilization machines**

Informazioni puntuali e aggiornate circa lo stato della presente Certificazione sono disponibili all'indirizzo [www.dasa-raegister.com](http://www.dasa-raegister.com).  
Punctual and updated information regarding this Certification is available at [www.dasa-raegister.com](http://www.dasa-raegister.com).

Riferirsi al Manuale Qualità per i dettagli delle singole esclusioni ai requisiti della Norma ISO 13485:2021.  
La validità del presente Certificato è subordinata al rispetto delle prescrizioni del Regolamento di Certificazione Dasa-Rägister, dei requisiti della ISO 13485:2021, ad un programma di sorveglianza annuale e ad un riesame ogni tre anni.

Refer to the Quality Manual for details regarding the exclusions to ISO 13485:2021 Standard requirements.  
The validity of this Certificate is subordinated by a full respect of that prescribed in Dasa-Rägister's Certification Regulation, of ISO 13485:2021 Standard requirements, to an annual surveillance programme and to a three yearly re-assessment.



# Dasa-Rägister

**IMD-0218-01**

Certificato n.  
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Dasa-Rägister S.p.A.

certifica che il sistema di gestione per la qualità di  
certifies that the quality management system of

## S.M.I. MEDICAL S.r.l.

Italia - 54033 - Carrara (MS) - Via Rinchiosa, 20/C - Frazione Marina - Sede  
Legale

è stato verificato e trovato conforme ai requisiti dello standard  
has been assessed and found in compliance with the standard requirements

## UNI CEI EN ISO 13485:2021

per il sito  
for the site

Italia - 56035 - Casciana Terme Lari (PI) - Via Piemonte, 112

per le seguenti attività aventi come oggetto

**Progettazione, produzione, immissione in commercio, assistenza tecnica e convalida di sterilizzatrici a vapore, di macchine di lavaggio e disinfezione di strumentario chirurgico e di macchine di lavaggio e sterilizzazione di strumenti endoscopici**

for the following activities having as object

**Design, production, placing on the market, technical assistance and validation of steam sterilizers, of surgical instrument cleaning and disinfection machines, endoscopic instruments cleaning and sterilization machines**

Informazioni puntuali e aggiornate circa lo stato della presente Certificazione sono disponibili all'indirizzo [www.dasa-raegister.com](http://www.dasa-raegister.com).  
Punctual and updated information regarding this Certification is available at [www.dasa-raegister.com](http://www.dasa-raegister.com).

Riferirsi al Manuale Qualità per i dettagli delle singole esclusioni ai requisiti della Norma ISO 13485:2021.  
La validità del presente Certificato è subordinata al rispetto delle prescrizioni del Regolamento di Certificazione Dasa-Rägister, dei requisiti della Norma ISO 13485:2021, ad un programma di sorveglianza annuale e ad un riesame ogni tre anni.

Refer to the Quality Manual for details regarding the exclusions to ISO 13485:2021 Standard requirements.  
The validity of this Certificate is subordinated by a full respect of that prescribed in Dasa-Rägister's Certification Regulation, of ISO 13485:2021 Standard requirements, to an annual surveillance programme and to a three yearly re-assessment.



# Dasa-Rägister

**IPDR-0324-02**

Certificato n.  
Certificate n.

**2024-03-01**

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C.E.O.

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Dasa-Rägister S.p.A.

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## S.M.I. MEDICAL S.r.l.

Italia - 54033 - Carrara (MS) - Via Rinchiosa, 20/C - Frazione Marina - Sede  
Legale

è stato verificato e trovato conforme ai requisiti dello standard  
has been assessed and found in compliance with the standard requirements

### UNI/PdR 125:2022

per il sito  
for the site

Italia - 56035 - Casciana Terme Lari (PI) - Via Piemonte, 112

per le seguenti attività aventi come oggetto

**Misure per garantire la parità di genere nel contesto lavorativo relativamente alle seguenti attività: progettazione, produzione, commercializzazione, assistenza tecnica e validazione di sterilizzatrici a vapore, di macchine di lavaggio e disinfezione di strumentario chirurgico e di macchine di lavaggio e sterilizzazione di strumenti endoscopici**

for the following activities having as object

**Measures taken to ensure gender equality in the workplace regarding the following activities: design, production, commercialization, technical assistance and validation of steam sterilizers of surgical instrument cleaning and disinfection machines, endoscopic instruments cleaning and sterilization machines**



Informazioni puntuali e aggiornate circa lo stato della presente Certificazione sono disponibili all'indirizzo [www.dasa-raegister.com](http://www.dasa-raegister.com)  
Punctual and updated information regarding this Certification is available at [www.dasa-raegister.com](http://www.dasa-raegister.com)

La validità del presente Certificato è subordinata al rispetto delle prescrizioni del Regolamento di Certificazione Dasa-Rägister, dei requisiti della Norma UNI/PdR 125:2022, ad un programma di sorveglianza annuale e ad un riesame ogni tre anni.  
The validity of this Certificate is subordinated by a full respect of that prescribed in Dasa-Rägister's Certification Regulation, of UNI/PdR 125:2022, Standard requirements, to an annual surveillance programme and to a three yearly re-assessment.

**DICHIARAZIONE DI CONFORMITÀ UE  
DECLARATION OF CONFORMITY EU**



Denominazione prodotto / *Product Name*

**Trattamento rifiuti  
Waste treatment**

**T25**

Ordine - Serie N. / *Order - Series N°*

**SMI-xxxxx**

*La macchina è conforme ai dettami delle seguenti Direttive Nazionali e Comunitarie:  
Direttiva Europea 2006/42/CE Direttiva macchine  
Direttiva Europea 2014/35/UE Bassa tensione  
Direttiva Europea 2014/30/UE Compatibilità Elettromagnetica*

*In particolare soddisfa le seguenti Norme Armonizzate:*

*The machine complies with the regulations in the following Italian and European Directives:  
2006/42/ EC Machinery Directive  
2014/35/ EU Low Voltage Directive  
2014/30/ EU Electromagnetic Compatibility  
In particular, it complies with the following Harmonized Standards:*

**UNI EN 285:2009 ; EN ISO 14971:2012; EN 62304:2006 ; EN 62366:2008**

**CEI EN 61010-1:2010; CEI EN 61010-2-040:2005**

Luogo e data / *Place and date / Lieu et date /*

**Pisa, 2026 February 20**

*Ort und Datum / Lugar y fecha*

Fabbricante / *Manufacturer:*

S.M.I. Medical S.r.l.

Via Rinchiosa, 20 C

I – 54033 Marina di Carrara [MS]

CEO

Alessio lenzi

## Electromagnetic Compatibility (EMC) Test report N° 2408061125 rev.0

Report N° ..... : 2408061125  
Project ID ..... : 073-24  
EUT code..... : 073-24\_2  
Inventory code ..... : 073-24\_2  
Date of receipt of test item..... : 31/05/2024  
Date(s) of performance of tests .... : from 03/06/2024 to 03/06/2024

### Report Emission&Verification

Compiled by..... : Mirko Prandi  
(Test operator)  
Approved by ..... : Francesco Barbierato  
(Laboratory Manager)  
Date of issue..... : August 06, 2024



### Testing laboratory

Name ..... : InLAB S.r.l.  
Address ..... : Via L.V. Beethoven, 46/A 42122 Reggio Emilia (RE) - Italy  
Testing location ..... : Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy

### Applicant

Company name ..... : SMI MEDICAL S.R.L.  
Address ..... : Via Piemonte, 112 - 56035 Casciana Terme Lari (PI) - Italy  
Contact person ..... : Eros De Pian E-mail: info@smimedical.it

### Test specification

Applied standard(s) ..... : EN 61326-1:2013  
EN 61326-1:2021

### Test item(EUT)

Description..... : Shredding and Sterilization of Hazardous Waste, T-series  
Trademark ..... :   
Model and/or type reference..... : Truster T50 -T25 -T10  
Manufacturer ..... : SMI MEDICAL S.R.L.  
Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy

### Test Result(s)

For further details, pls. refer to the following pages

*The test results presented in this report relate only to the object tested.. This report shall not be reproduced, except in full, without the written approval of the Testing Laboratory.  
The authenticity of this Test Report and its contents can be verified by contacting the Testing Laboratory, responsible for this Test Report.*



**Document info**

Document N° of pages ..... : 51  
 Report N° of pages ..... : 50  
 Annex N° of pages..... : 1  
 Test Report Form No. .... : Report\_BaseTemplate\_rev.0\_240229  
 Standard Form(s) No..... : None  
 Forms originator ..... : InLAB S.r.l.

**Revision History**

Rev N°	Date	Revision description	Approved By
0	06/08/2024	First issue	Francesco Barbierato <i>(Laboratory Manager)</i>



**Table of Contents:**

1	Test report details .....	4
1.1	Abbreviations and Acronyms .....	4
1.2	Possible test case verdicts.....	4
1.3	Measurement uncertainties.....	4
1.4	General remarks.....	4
2	General description of test item(s) .....	5
2.1	General Info .....	5
2.2	Block diagram .....	6
2.3	Ports description.....	6
2.4	Test item pictures.....	6
2.5	Test item identification label.....	7
2.6	Provided documents .....	8
2.7	Sampling.....	8
2.8	Modifications to the test item(EUT) during testing .....	8
2.9	Accessories.....	8
3	Test conditions.....	9
3.1	General.....	9
3.2	Operating modes.....	9
4	Test method(s) and Test Verdict(s).....	10
4.1	Test method EN IEC 61326-1:2021.....	10
4.2	Test method EN 61326-1:2013 .....	14
5	EN 61326-1_Test results.....	18
5.1	Conducted emission(Mains Port).....	18
5.2	Radiated emission.....	24
5.3	Electrostatic discharge (ESD).....	33
5.4	Electromagnetic field.....	39
5.5	Fast transients, Burst.....	43
5.6	Radio frequency common mode .....	47
	Annex section.....	1



# 1 Test report details

## 1.1 Abbreviations and Acronyms

N.D.:	Not Declared	AC:	Alternating Current
N/A:	Not Applicable	DC:	Direct Current
EUT:	Equipment under test / Test Item	OATS:	Open Area Test Site
AE:	Auxiliary/Associated equipment	SAC:	Semi anechoic chamber
AMN:	Artificial Mains Network(LISN)	FAR:	Full anechoic room
AAN:	Asymmetric Artificial Network	GTEM:	Gigahertz Transverse ElectroMagnetic
CP:	Current probe		
CVP:	Current voltage probe		
GRP:	Ground plane		
HCP:	Horizontal coupling plane		
VCP:	Vertical coupling plane		
UFA:	Uniform field area		
CDN:	Coupling decoupling network		

## 1.2 Possible test case verdicts

- test case does not apply to the test object .....	N/A
- test case does not required by the applicant.....	N/R
- test object does meet the requirement .....	P (Pass)
- test object does not meet the requirement .....	F (Fail)

## 1.3 Measurement uncertainties

For all measurements where guidance for the calculation of the instrumentation uncertainty of a measurement is specified in CISPR 16-4-2, IEC 61000-4 series or a product standard, the measurement instrumentation uncertainty has been calculated and applied in accordance with these standards. In all cases if the test laboratory uncertainty is larger than the value for  $U_{CISPR}$  given in CISPR 16-4-2 the uncertainty is included in the test report annex. In case the standards in the IEC 61000-4 series or the product standard requires the indication of the uncertainty in the report these uncertainty values are included in the annex.

## 1.4 General remarks

"(See Enclosure #)" refers to additional information appended to the report.  
 "(See appended table)" refers to a table appended to the report.  
 Throughout this report a comma ☒ / ☐ point is used as the decimal separator.  
 Date format: Day/Month/Year

Name and address of factory (ies): Via  
 Piemonte, 112 - 56035 Casciana Terme Lari  
 (PI) - Italy

## 2 General description of test item(s)

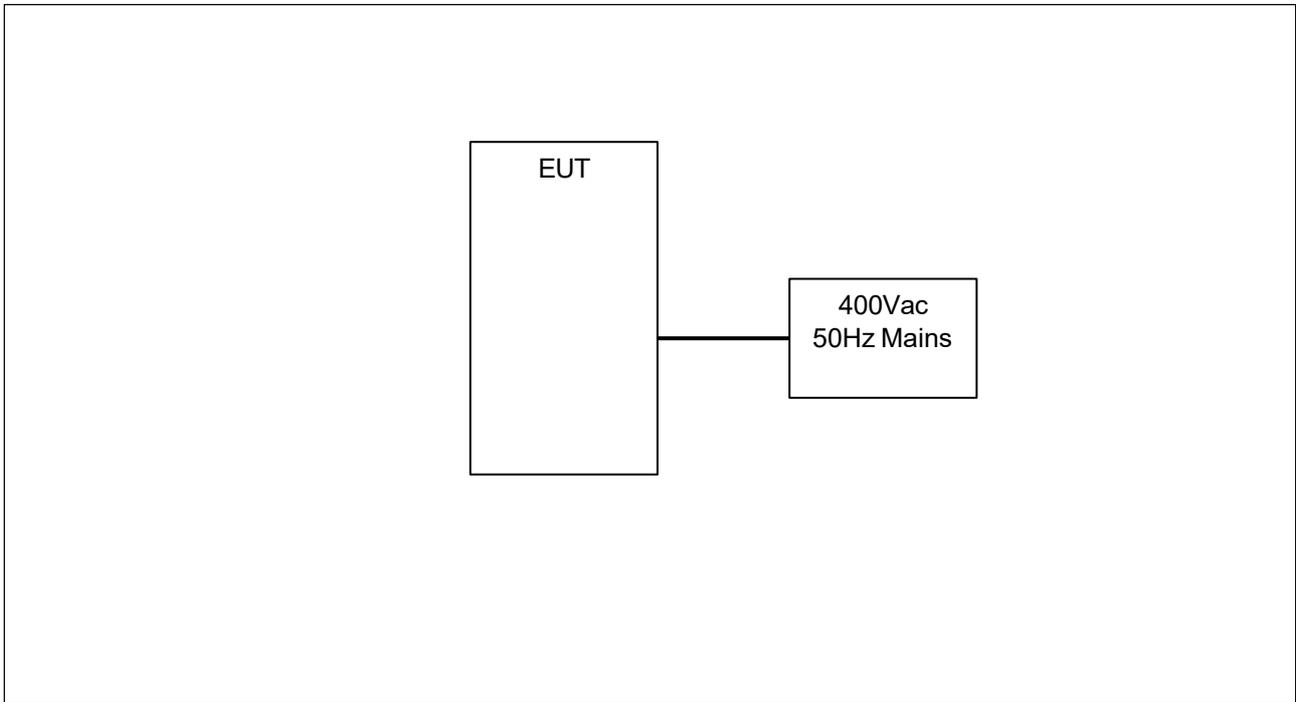
*Customer declared data*

### 2.1 General Info

Description .....	Shredding and Sterilization of Hazardous Waste, T-series					
Model number .....	Truster T50					
Serial number.....	SMI-01364					
Rated power supply .....	<b>Voltage and frequency</b>					<b>L1</b>
	<input checked="" type="checkbox"/>	AC: 400 V / 50 Hz				<input checked="" type="checkbox"/>
Rated power.....	100 kW					
Protection class.....	Class I (PE connection present)					
Clock frequencies.....	not declared by the Client					
Other parameters .....	not relevant for EMC point of view					
Software version .....	not declared by the Client					
Hardware version .....	not declared by the Client					
Dimensions (W x H x D).....	not declared by the Client					
Weight: .....	not declared by the Client					
Mounting position .....	<input type="checkbox"/>	Table top equipment				
	<input type="checkbox"/>	Wall/Ceiling mounted equipment				
	<input checked="" type="checkbox"/>	Floor standing equipment				
	<input type="checkbox"/>	Hand-held equipment				
	<input type="checkbox"/>	Other:				
Test configuration .....	Floor standing					
Modules / parts.....	Module / parts of test item	Type	Manufacturer			
	--	--	--			
	--	--	--			
	--	--	--			
	--	--	--			
	--	--	--			
	--	--	--			



## 2.2 Block diagram



## 2.3 Ports description

N°	Type	Description	Specified max length[m]	Connection	Connected during test	Shielded	Notes
P#1	Enclosure	P#1_Enclosure	//	//	<input checked="" type="checkbox"/>	<input type="checkbox"/>	//
P#2	AC Mains input	P#2_TP_AC_IN1_400VAC	//	L1, L2, L3, N, PE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	//

## 2.4 Test item pictures



## 2.5 Test item identification label

<b>CE</b>	<b>SMI</b> MEDICAL	 SMI Medical s.r.l. Via Rinchiosa 20 C 54033 Marina di Carrara (MS)			
REF	T50				
SN	SMI-01364	09-2023			
V	400	KW	100	Hz	50
Cod. SMI-000101					

<b>SMI</b> MEDICAL	 SMI Medical s.r.l. Via Rinchiosa 20 C 54033 Marina di Carrara (MS)	 					
REF	T50						
SN	SMI-01364						
V	400	PH	3PH+N+E	KW	100	Hz	50
Icc=	10	KA	Nr SMI20373				
Cod. SMI-000102							



## 2.6 Provided documents

Documents as provided by the applicant:	Description	File name	Issue date
	No documents provided	--	--
	--	--	--

## 2.7 Sampling

Equipment under test (EUT) sampling is on Applicant's charge and responsibility

## 2.8 Modifications to the test item(EUT) during testing

No additional shielding, ferrites, capacitors, filters etc. were applied during the performed tests.

## 2.9 Accessories

Accessories .....: (not part of the test item)	Accessory	Type	Manufacturer
	--	--	--



### 3 Test conditions

#### 3.1 General

Environmental reference conditions .....	The climatic conditions during the tests are within the limits specified by the manufacturer for the operation of the EUT and the test equipment. The climatic conditions during the tests were within the following limits:		
	<b>Temperature</b>	<b>Humidity</b>	<b>Atmospheric pressure</b>
	15 °C ÷ 35 °C	30 % ÷ 60 %	860 hPa ÷ 1060 hPa
	If explicitly required in the basic standard or applied product standard the climatic values are recorded and documented separately in this test report.		

#### 3.2 Operating modes

Operating modes .....	No.	Operating mode of test item
	OM#1	Power ON, completely Operative
	OM#2	Power ON, completely Operative
Supplemental information to the operating modes .....	--	



## 4 Test method(s) and Test Verdict(s)

### 4.1 Test method EN IEC 61326-1:2021

Method	Title
EN IEC 61326-1:2021	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

#### 4.1.1 Reference standards

Method	Title
EN IEC 61000-3-2:2019	Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current $\leq 16$ A per phase)
EN 61000-3-3:2013 EN 61000-3-3:2013/A1:2019	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current $\leq 16$ A per phase and not subject to conditional connection
EN IEC 61000-3-11:2019	Electromagnetic compatibility (EMC) – Part 3-11: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems – Equipment with rated current $\leq 75$ A and subject to conditional connection
EN 61000-3-12:2011	Electromagnetic compatibility (EMC) - Part 3-12: Limits - Limits for harmonic currents produced by equipment connected to public low-voltage systems with input current $> 16$ A and $\leq 75$ A per phase
EN 61000-4-2:2009	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
EN 61000-4-3:2006 EN 61000-4-3:2006 /A1:2008 EN 61000-4-3:2006 /A2:2010	Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
EN 61000-4-4:2012	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
EN 61000-4-5:2014 EN 61000-4-5:2014 /A1:2017	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
EN 61000-4-6:2014	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
EN 61000-4-8:2010	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
EN IEC 61000-4-11:2020	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase
EN 55011:2016 EN 55011:2016/A1:2017 EN 55011:2016/A11:2020 EN 55011:2016 /A2:2021	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement



#### 4.1.2 Equipment classification according reference standard

Emission tests classification	<input checked="" type="checkbox"/> Group 1 equipment,acc CISPR 11:2015, par.5.1
	<input type="checkbox"/> Group 2 equipment,acc CISPR 11:2015, par.5.1
	<input checked="" type="checkbox"/> Class A equipment,acc CISPR 11:2015, par.5.2
	<input type="checkbox"/> Class B equipment,acc CISPR 11:2015, par.5.2

Immunity tests classification	<input type="checkbox"/> Equipment intended to be used in a BASIC ELECTROMAGNETIC ENVIRONMENT(Par.6, Tab.1)
	<input type="checkbox"/> Equipment intended to be used in an INDUSTRIAL ELECTROMAGNETIC ENVIRONMENT(Par.6, Tab.2)
	<input checked="" type="checkbox"/> Equipment intended to be used in a CONTROLLED ELECTROMAGNETIC ENVIRONMENT(Par.6, Tab.3)



### 4.1.3 Performance criteria definition for EMC Immunity tests

Performance criteria as defined by the standard (see §6.4 of the EN61326-1)	
The general principles (performance criteria) for the evaluation of the immunity test results are the following. Permissible LOSSES OF PERFORMANCE are allowed only if specified in the test plan before testing, and clearly provided to the user in the product specification. If the PERFORMANCE LEVEL or the permissible LOSS OF PERFORMANCE is not specified, either of these may be derived from the product specification or user documentation and what the user may reasonably expect from the equipment if used as intended.	
A	The equipment shall continue to operate as intended during and after the test. No DEGRADATION OF PERFORMANCE or LOSS OF FUNCTION is allowed below a PERFORMANCE LEVEL specified in the user documentation, when the equipment is used as intended. In the case of applying immunity tests with continuous electromagnetic phenomena, the PERFORMANCE LEVEL may be replaced by a permissible LOSS OF PERFORMANCE which shall recover, without user intervention. A permissible LOSS OF PERFORMANCE is allowed within the PERFORMANCE LEVEL only when this information is clearly provided to the end user via documentation, such as the product user manual. No change in the operating state is allowed nor is loss of data.
B	The equipment shall continue to operate as intended after the test. No DEGRADATION OF PERFORMANCE or LOSS OF FUNCTION is allowed below a PERFORMANCE LEVEL specified in the user documentation, when the equipment is used as intended. During the test, the equipment PERFORMANCE LEVEL may be replaced by a permissible LOSS OF PERFORMANCE if such LOSS OF PERFORMANCE is detailed in the EMC test plan. A permissible LOSS OF PERFORMANCE is allowed within the PERFORMANCE LEVEL only when this information is clearly provided to the end user via documentation, such as the product user manual. An unintended change of the operating state is allowed if self-recoverable. No loss of stored data is allowed.  <i>The following are examples of performance criterion B:</i> <ul style="list-style-type: none"> <li>• Data transfer is controlled or checked by parity check or by other means. In the case of malfunction, such as caused by a surge impulse, the data transfer will be repeated automatically. A reduced data transfer rate at this time is allowable degradation.</li> <li>• During testing, an analogue function value may deviate in excess of the specified limits. After the test, the deviation vanishes.</li> <li>• In the case of a monitor used only for man-machine monitoring, it is allowable that some degradation takes place, such as momentary display interference during the application of burst impulses.</li> </ul>
C	LOSS OF FUNCTION is allowed, provided the function is self-recoverable or can be restored by the operation of the controls. Recovery procedure shall be included in the user documentation. No permanent damage to the equipment is allowed.  <i>The following are examples of performance criterion C:</i> <ul style="list-style-type: none"> <li>• In the case of an interruption in the mains longer than the specified buffer time, the power supply unit of the equipment is switched off. The switch-on may be automatic or carried out by the operator.</li> <li>• After a programme interruption caused by a disturbance, the processor functions of the equipment stops at a defined position and is not left in a "crashed state". An operator's action may be necessary.</li> </ul>

#### Performance criterion as defined by the manufacturer

A	See Standard criteria definition
B	See Standard criteria definition
C	See Standard criteria definition

#### Monitored parameters

N°	Parameter/EUT Function	Monitored BY	Monitoring type
1	Information about the operative cycle shown on touch screen	InLab - Test Operator	Visual
2			
3			
4			
5			



#### 4.1.4 Verdict Summary

EN IEC 61326-1:2021-06		Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General requirements						
		<input checked="" type="checkbox"/> Full application of the standard <input type="checkbox"/> Partial application of the standard						
Rep ref.	Phenomenon	Ref.Standard	Test value / Test limit	Port	Op. Mode	Required criterion	Observed criterion	Verdict
5.1	Conducted emission	EN 61326-1 (par.7) EN 55011	EN 55011 Class A, Group 1	P#1_AC port	OM#1	Emi<Lim	///	PASS
5.2	Radiated emission	EN 61326-1 (par.7) EN 55011	EN 55011 Class A, Group 1	P#1_Enclosure	OM#1	Emi<Lim	///	PASS
-	Mains Harmonics	EN 61326-1 (par.7) EN 61000-3-2	Professional Use	P#1_AC port	OM#1	Emi<Lim	///	-
-	Voltage fluctuations and flicker	EN 61326-1 (par.7) EN 61000-3-11	Installation under special conditioning	P#1_AC port	OM#1	Emi<Lim	///	-
5.3	Electrostatic discharge (ESD)	EN 61326-1 (par.6, Tab.3) EN 61000-4-2	±4 kV contact ±8 kV air	P#1_Enclosure	OM#1	B	A	PASS
5.4	Electromagnetic field	EN 61326-1 (par.6, Tab.3) EN 61000-4-3	1 V/m (80 MHz to 1 GHz) 1 V/m (1,4 GHz to 2 GHz) 1 V/m (2,0 GHz to 2.7 GHz)	P#1_Enclosure	OM#1	A	A	PASS
5.5	Burst_AC power	EN 61326-1 (par.6, Tab.2) EN 61000-4-4	±1 kV (5 kHz or 100 kHz)	P#1_AC port	OM#1	B	A	PASS
-	Burst_DC power (including protective earth)	EN 61326-1 (par.6, Tab.3) EN 61000-4-4	±1 kV (5 kHz or 100 kHz)	-	OM#1	B		N/A
-	Burst_I/O signal/control (including functional earth)	EN 61326-1 (par.6, Tab.3) EN 61000-4-4	±0.5kV (5 kHz or 100 kHz)	P#x_I/O	OM#1	B		N/A
-	Surge_AC power	EN 61326-1 (par.6, Tab.3) EN 61000-4-5	±0.5 kV line-to-line ±1 kV line-to-ground	P#1_AC port	OM#1	B		N/A
5.6	Conducted RF_AC Power	EN 61326-1 (par.6, Tab.3) EN 61000-4-6	1 V (150 kHz to 80 MHz)	P#1_AC port	OM#1	A	A	PASS
-	Conducted RF_DC Power (including protective earth)	EN 61326-1 (par.6, Tab.3) EN 61000-4-6	1 V (150 kHz to 80 MHz)	-	OM#1	A		N/A
-	Conducted RF_I/O signal/control (including functional earth)	EN 61326-1 (par.6, Tab.3) EN 61000-4-6	1 V (150 kHz to 80 MHz)	P#x_I/O	OM#1	A		N/A

Table 1 – Immunity test requirements for equipment intended to be used in a CONTROLLED ELECTROMAGNETIC ENVIRONMENT

test case does not apply to the test object	N/A
test not required by the applicant	N/R
test object does meet the requirement	P (Pass)
test object does not meet the requirement	F (Fail)



## 4.2 Test method EN 61326-1:2013

Method	Title
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General requirements

### 4.2.1 Reference standards

Method	Title
EN 61000-3-2:2006 EN 61000-3-2:2006/A1:2009 EN 61000-3-2:2006/A2:2009	Electromagnetic compatibility (EMC) – Part 3-2: Limits - Limits for harmonic current emissions (equipment input current $\leq 16$ A per phase)
EN 61000-3-3:2008	Electromagnetic compatibility (EMC) – Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current $\leq 16$ A per phase and not subject to conditional connection
EN 61000-3-11:2000	Electromagnetic compatibility (EMC) – Part 3-11: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems - Equipment with rated current $\leq 75$ A and subject to conditional connection
EN 61000-3-12:2011	Electromagnetic compatibility (EMC) – Part 3-12: Limits - Limits for harmonic currents produced by equipment connected to public low-voltage systems with input current $> 16$ A and $\leq 75$ A per phase
EN 61000-4-2:2009	Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
EN 61000-4-3:2006 EN 61000-4-3:2006/A1:2008 EN 61000-4-3:2006/A2:2010	Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
EN 61000-4-4:2004 EN 61000-4-4:2004/A1:2010	Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
EN 61000-4-6:2009	Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radiofrequency fields
EN 61000-4-8:2010	Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
EN 61000-4-11:2004	Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
EN 55011:2009 EN 55011:2009/A1:2010	Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics - Limits and methods of measurement



#### 4.2.2 Equipment classification according reference standard

Emission tests classification	<input checked="" type="checkbox"/> Group 1 equipment,acc CISPR 11:2009, par.5.1
	<input type="checkbox"/> Group 2 equipment,acc CISPR 11:2009, par.5.1
	<input type="checkbox"/> Class A equipment,acc CISPR 11:2009, par.5.2
	<input type="checkbox"/> Class B equipment,acc CISPR 11:2009, par.5.2

Immunity tests classification	<input type="checkbox"/> Equipment intended to be used in a BASIC ELECTROMAGNETIC ENVIRONMENT(Par.6, Tab.1)
	<input type="checkbox"/> Equipment intended to be used in an INDUSTRIAL ELECTROMAGNETIC ENVIRONMENT(Par.6, Tab.2)
	<input checked="" type="checkbox"/> Equipment intended to be used in a CONTROLLED ELECTROMAGNETIC ENVIRONMENT(Par.6, Tab.3)



#### 4.2.3 Performance criteria definition for EMC Immunity tests

Performance criteria as defined by the standard (see §6.4 of the EN61326-1)			
The general principles (performance criteria) for the evaluation of the immunity test results are the following.			
A	The equipment shall continue to operate as intended during and after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the equipment is used as intended. The performance level may be replaced by a permissible loss of performance. If the minimum performance level or the permissible performance loss is not specified by the manufacturer, either of these may be derived from the product description and documentation and what the user may reasonably expect from the equipment if used as intended.		
B	<p>The equipment shall continue to operate as intended after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the equipment is used as intended. The performance level may be replaced by a permissible loss of performance. During the test, degradation of performance is however allowed. No change of actual operating state or stored data is allowed. If the minimum performance level or the permissible performance loss is not specified by the manufacturer, either of these may be derived from the product description and documentation and what the user may reasonably expect from the equipment if used as intended.</p> <p><i>EXAMPLE 1 A data transfer is controlled/checked by parity check or by other means. In the case of malfunctioning, such as caused by a lightning strike, the data transfer will be repeated automatically. The reduced data transfer rate at this time is acceptable.</i></p> <p><i>EXAMPLE 2 During testing, an analogue function value may deviate. After the test, the deviation vanishes.</i></p> <p><i>EXAMPLE 3 In the case of a monitor used only for man-machine monitoring, it is acceptable that some degradation takes place for a short time, such as flashes during the burst application.</i></p> <p><i>EXAMPLE 4 An intended change of the operating state is allowed if self-recoverable.</i></p>		
C	<p>Temporary loss of function is allowed, provided the function is self-recoverable or can be restored by the operation of the controls.</p> <p><i>EXAMPLE 1 In the case of an interruption in the mains longer than the specified buffer time, the power supply unit of the equipment is switched off. The switch-on may be automatic or carried out by the operator.</i></p> <p><i>EXAMPLE 2 After a programme interruption caused by a disturbance, the processor functions of the equipment stops at a defined position and is not left in a "crashed state". The operator's decision prompts may be necessary.</i></p> <p><i>EXAMPLE 3 The test results in an opening of an over-current protection device that is replaced or reset by the operator.</i></p>		
<b>Performance criterion as defined by the manufacturer</b>			
A	See Standard criteria definition		
B	See Standard criteria definition		
C	See Standard criteria definition		
<b>Monitored parameters</b>			
N°	Parameter/EUT Function	Monitored BY	Monitoring type
1	Information about the operative cycle shown on touch screen	InLab - Test Operator	Visual
2			
3			
4			
5			



#### 4.2.4 Verdict Summary

EN 61326-1:2013		Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General requirements						
		<input checked="" type="checkbox"/> Full application of the standard <input type="checkbox"/> Partial application of the standard						
Rep ref.	Phenomenon	Ref.Standard	Test value / Test limit	Port	Op. Mode	Required criterion	Observed criterion	Verdict
5.1	Conducted emission	EN 61326-1 (par.7) EN 55011	EN 55011 Class A, Group 1	P#1_AC port	OM#1	Emi<Lim	///	PASS
5.2	Radiated emission	EN 61326-1 (par.7) EN 55011	EN 55011 Class A, Group 1	P#1_Enclosure	OM#1	Emi<Lim	///	PASS
--	Mains Harmonics	EN 61326-1 (par.7) EN 61000-3-2	Professional Use	P#1_AC port	OM#1	Emi<Lim	///	-
--	Voltage fluctuations and flicker	EN 61326-1 (par.7) EN 61000-3-3	Installation under special conditioning	P#1_AC port	OM#1	Emi<Lim	///	-
5.3	Electrostatic discharge (ESD)	EN 61326-1 (par.6, Tab.3) EN 61000-4-2	±4 kV contact ±8 kV air	P#1_Enclosure	OM#1	B	A	PASS
5.4	Electromagnetic field	EN 61326-1 (par.6, Tab.3) EN 61000-4-3	1 V/m (80 MHz to 1 GHz) 1 V/m (1,4 GHz to 2 GHz) 1 V/m (2,0 GHz to 2,7 GHz)	P#1_Enclosure	OM#1	A	A	PASS
5.5	Burst_AC power	EN 61326-1 (par.6, Tab.2) EN 61000-4-4	±1 kV (5 kHz or 100 kHz)	P#1_AC port	OM#1	B	A	PASS
--	Burst_DC power (including protective earth)	EN 61326-1 (par.6, Tab.3) EN 61000-4-4	±1 kV (5 kHz or 100 kHz)	-	OM#1	B		N/A
--	Burst_I/O signal/control (including functional earth)	EN 61326-1 (par.6, Tab.3) EN 61000-4-4	±0.5kV (5 kHz or 100 kHz)	P#x_I/O	OM#1	B		N/A
--	Surge_AC power	EN 61326-1 (par.6, Tab.3) EN 61000-4-5	±0.5 kV line-to-line ±1 kV line-to-ground	P#1_AC port	OM#1	B		N/A
5.6	Conducted RF_AC Power	EN 61326-1 (par.6, Tab.3) EN 61000-4-6	1 V (150 kHz to 80 MHz)	P#1_AC port	OM#1	A	A	PASS
--	Conducted RF_DC Power (including protective earth)	EN 61326-1 (par.6, Tab.3) EN 61000-4-6	1 V (150 kHz to 80 MHz)	-	OM#1	A		N/A
--	Conducted RF_I/O signal/control (including functional earth)	EN 61326-1 (par.6, Tab.3) EN 61000-4-6	1 V (150 kHz to 80 MHz)	P#x_I/O	OM#1	A		N/A

Table 1 – Immunity test requirements for equipment intended to be used in a CONTROLLED ELECTROMAGNETIC ENVIRONMENT

test case does not apply to the test object	N/A
test not required by the applicant	N/R
test object does meet the requirement	P (Pass)
test object does not meet the requirement	F (Fail)



## 5 EN 61326-1\_Test results

### 5.1 Conducted emission(Mains Port)

#### 5.1.1 Test setup

<input checked="" type="checkbox"/>	Test setup according reference standard has been realized
<input type="checkbox"/>	Test setup according reference standard has been realized with following deviations

#### 5.1.2 Test setup Pictures



#### 5.1.3 Instruments used for the test

Internal N°	Description	Type/Model	Manufacturer	Serial N°
E015	Spectrum Analyzer	SSA3075X Plus	Siglent	SSA5PEAC5R0002
E020	RF Voltage-Probe	TK9420	Schwarzbeck	1082
E021	Plug-In Divider 6 dB(1,5kΩ)	VT9420	Schwarzbeck	4867
ER01	N-N_8m	Sucoflex 404A_N-N_8m	Huber&Suhner	113

#### 5.1.4 Software

Internal N°	Development company	Name	Version	Year
S001	Rohde & Schwarz	ES-K1	1.71	2003

#### 5.1.5 Accessories

Internal N°	Description	Type/Model	Manufacturer	Serial N°
--	--	--	--	--



**5.1.6 Test details**

Reference standard .....	EN 55011																	
Tested by .....	Francesco Barbierato																	
Test date .....	03/06/2024																	
Test location.....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy																	
Environmental conditions .....	<table border="1"> <thead> <tr> <th>Parameter</th> <th>Ref. Std.Limit</th> <th>Actual</th> </tr> </thead> <tbody> <tr> <td>Temperature (°C)</td> <td>--(15÷35)</td> <td>23</td> </tr> <tr> <td>Humidity (% rh)</td> <td>--(30÷60)</td> <td>40</td> </tr> </tbody> </table>	Parameter	Ref. Std.Limit	Actual	Temperature (°C)	--(15÷35)	23	Humidity (% rh)	--(30÷60)	40								
Parameter	Ref. Std.Limit	Actual																
Temperature (°C)	--(15÷35)	23																
Humidity (% rh)	--(30÷60)	40																
EUT Setup Type .....	Floor standing																	
Test method .....	Voltage Probe																	
Port(s) .....	AC power port's phases																	
Frequency Band .....	0.15÷30MHz																	
Limits .....	<b>EN 55011, Class A, Group 1, ≤75kVA</b> <table border="1"> <thead> <tr> <th rowspan="2">Frequency Band</th> <th colspan="2">Limit</th> </tr> <tr> <th>Quasi Peak detector</th> <th>Average detector</th> </tr> <tr> <th>MHz</th> <th>dB(μV)</th> <th>dB(μV)</th> </tr> </thead> <tbody> <tr> <td>0.15÷0.50</td> <td>100</td> <td>90</td> </tr> <tr> <td>0.50÷5</td> <td>86</td> <td>76</td> </tr> <tr> <td>5÷30</td> <td>90 to 73*</td> <td>80 to 60*</td> </tr> </tbody> </table> <small>*Linearly decreasing with logarithm of frequency</small>	Frequency Band	Limit		Quasi Peak detector	Average detector	MHz	dB(μV)	dB(μV)	0.15÷0.50	100	90	0.50÷5	86	76	5÷30	90 to 73*	80 to 60*
Frequency Band	Limit																	
	Quasi Peak detector	Average detector																
MHz	dB(μV)	dB(μV)																
0.15÷0.50	100	90																
0.50÷5	86	76																
5÷30	90 to 73*	80 to 60*																
Operating Mode(s).....	<table border="1"> <tr> <td>OM#1</td> <td>Power ON, completely Operative</td> </tr> <tr> <td>OM#2</td> <td>Power ON, completely Operative</td> </tr> </table>	OM#1	Power ON, completely Operative	OM#2	Power ON, completely Operative													
OM#1	Power ON, completely Operative																	
OM#2	Power ON, completely Operative																	
Notes .....																		

**5.1.7 Test result**

	OM#1
Equipment does COMPLY the requirements of this section	<input checked="" type="checkbox"/>
Equipment does NOT COMPLY this section	<input type="checkbox"/>

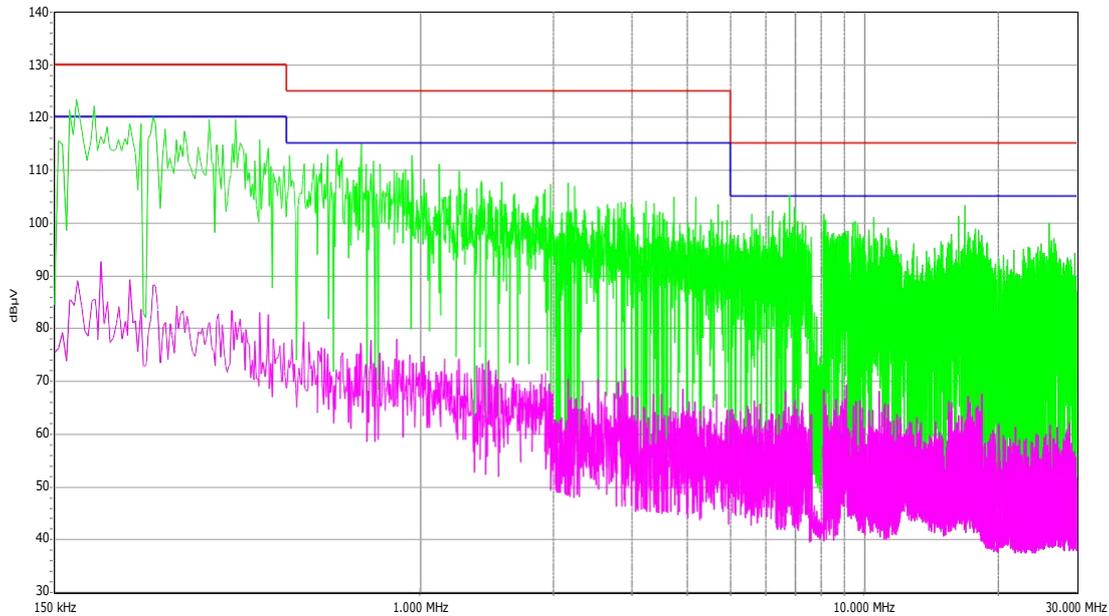
	OM#1	OM#2	OM#3	OM#4	OM#5
Equipment does COMPLY the requirements of this section	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Equipment does NOT COMPLY this section	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



5.1.8 Test data

5.1.8.1 Graphics

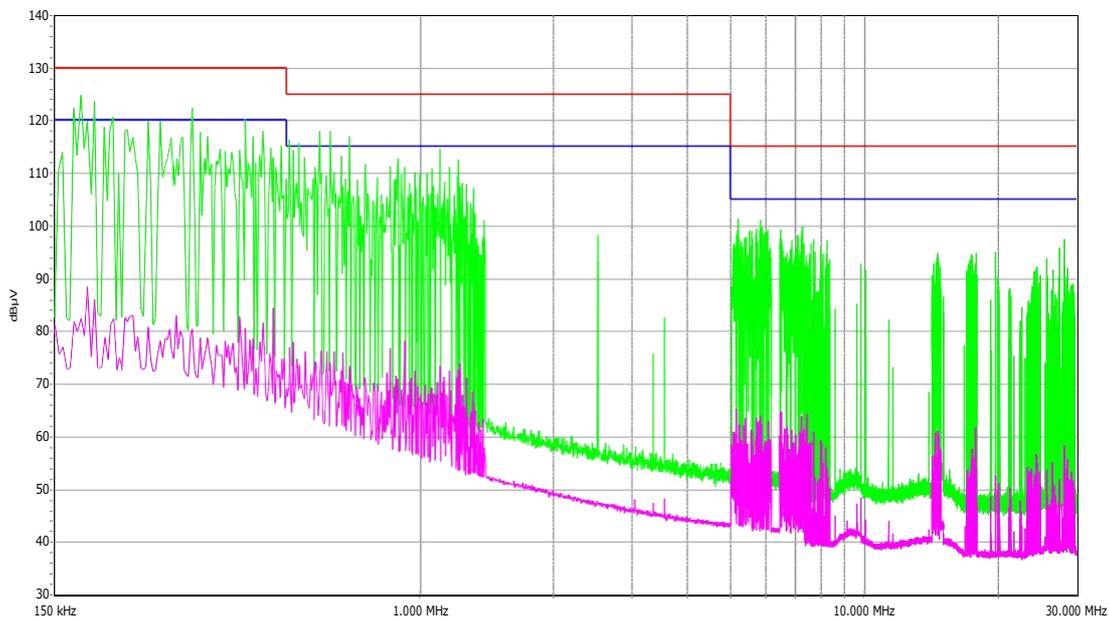
Description.....	: Shredding and Sterilization of Hazardous Waste, T-series
Trademark .....	: SCHLUMBOHM
Model and/or type reference....	: Truster T50
Manufacturer .....	: SMI MEDICAL S.R.L
Applicant .....	: SMI MEDICAL S.R.L
Test Location .....	: Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy
Test Engineer.....	: Francesco Barbierato
Method used.....	: EN 55011
Operating condition .....	: OM#1
Phase .....	: L1
Notes .....	: Peak and Average detector



Legenda.....	:  QP Limit Line  AV Limit Line  Measured Value MaxPeak  Measured Value Average																		
Receiver settings .....	: <table border="1" data-bbox="614 1758 1380 1848"> <thead> <tr> <th>Frequency range</th> <th>Detector</th> <th>Dwell time</th> <th>Res.BW</th> <th>Att.</th> <th>Preamp</th> </tr> </thead> <tbody> <tr> <td>0.15+30MHz</td> <td>Peak Average</td> <td>20ms</td> <td>10kHz</td> <td>10dB</td> <td>//</td> </tr> <tr> <td>0.15+30MHz</td> <td>Quasi-Peak(Final) Average(Final)</td> <td>1s</td> <td>10kHz</td> <td>10dB</td> <td>//</td> </tr> </tbody> </table>	Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp	0.15+30MHz	Peak Average	20ms	10kHz	10dB	//	0.15+30MHz	Quasi-Peak(Final) Average(Final)	1s	10kHz	10dB	//
Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp														
0.15+30MHz	Peak Average	20ms	10kHz	10dB	//														
0.15+30MHz	Quasi-Peak(Final) Average(Final)	1s	10kHz	10dB	//														



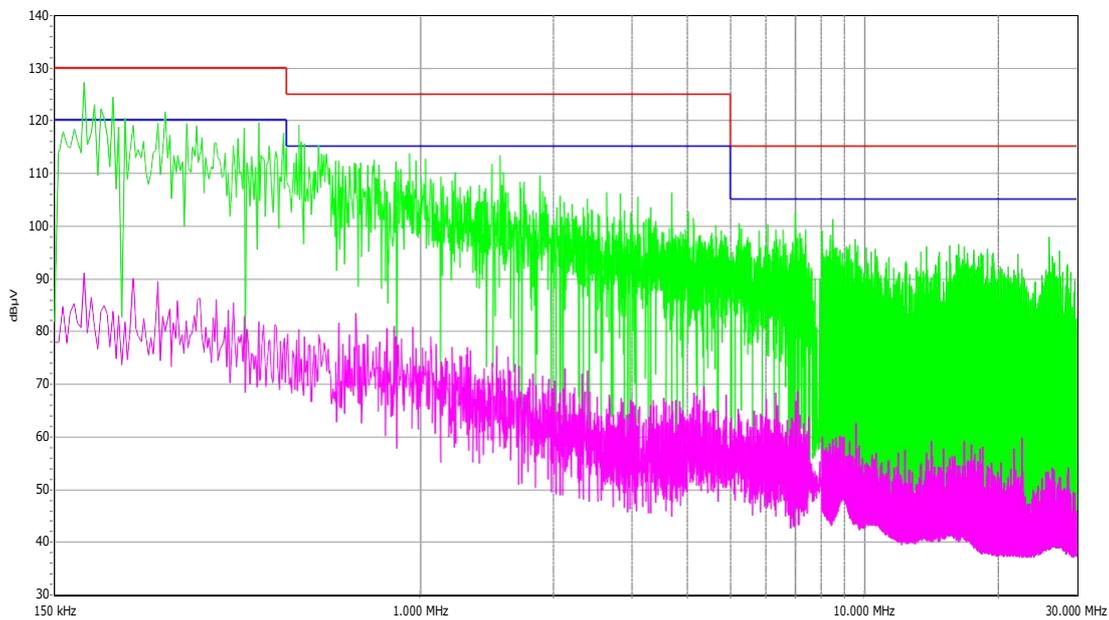
Description..... :	Shredding and Sterilization of Hazardous Waste, T-series
Trademark .....	SCHLUMBOHM
Model and/or type reference.... :	Truster T50
Manufacturer .....	SMI Medical S.r.l.
Applicant .....	SMI MEDICAL S.R.L
Test Location .....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy
Test Engineer..... :	Francesco Barbierato
Method used..... :	EN 55011
Operating condition .....	OM#1
Phase .....	L2
Notes .....	Peak and Average detector



Legenda..... :	<ul style="list-style-type: none"> <li><span style="color: red;">—</span> QP Limit Line</li> <li><span style="color: blue;">—</span> AV Limit Line</li> <li><span style="color: green;">—</span> Measured Value</li> <li><span style="color: green;">—</span> MaxPeak</li> <li><span style="color: purple;">—</span> Measured Value</li> <li><span style="color: purple;">—</span> Average</li> </ul>																		
Receiver settings .....	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Frequency range</th> <th>Detector</th> <th>Dwell time</th> <th>Res.BW</th> <th>Att.</th> <th>Preamp</th> </tr> </thead> <tbody> <tr> <td>0.15÷30MHz</td> <td>Peak Average</td> <td>20ms</td> <td>10kHz</td> <td>10dB</td> <td>//</td> </tr> <tr> <td>0.15÷30MHz</td> <td>Quasi-Peak(Final) Average(Final)</td> <td>1s</td> <td>10kHz</td> <td>10dB</td> <td>//</td> </tr> </tbody> </table>	Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp	0.15÷30MHz	Peak Average	20ms	10kHz	10dB	//	0.15÷30MHz	Quasi-Peak(Final) Average(Final)	1s	10kHz	10dB	//
Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp														
0.15÷30MHz	Peak Average	20ms	10kHz	10dB	//														
0.15÷30MHz	Quasi-Peak(Final) Average(Final)	1s	10kHz	10dB	//														



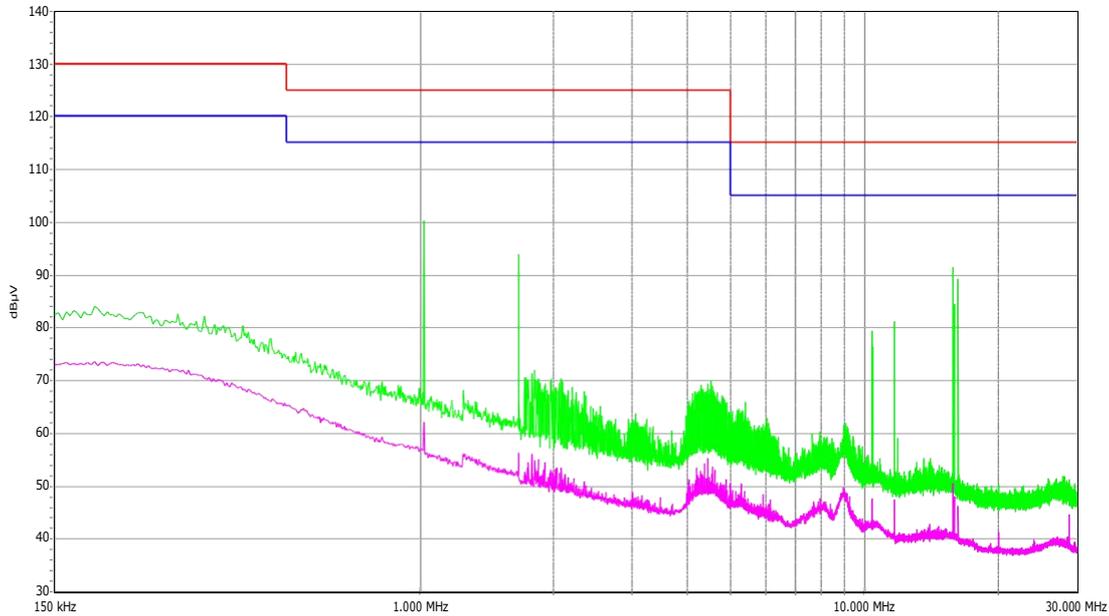
Description..... :	Shredding and Sterilization of Hazardous Waste, T-series
Trademark .....	SCHLUMBOHM
Model and/or type reference.... :	Truster T50
Manufacturer .....	SMI Medical S.r.l.
Applicant .....	SMI MEDICAL S.R.L
Test Location .....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy
Test Engineer..... :	Francesco Barbierato
Method used..... :	EN 55011
Operating condition .....	OM#1
Phase .....	L3
Notes .....	Peak and Average detector



Legenda..... :	<ul style="list-style-type: none"> <li><span style="color: red;">—</span> QP Limit Line</li> <li><span style="color: blue;">—</span> AV Limit Line</li> <li><span style="color: green;">—</span> Measured Value</li> <li><span style="color: green;">—</span> MaxPeak</li> <li><span style="color: purple;">—</span> Measured Value</li> <li><span style="color: purple;">—</span> Average</li> </ul>																		
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Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp														
0.15+30MHz	Peak Average	20ms	10kHz	10dB	//														
0.15+30MHz	Quasi-Peak(Final) Average(Final)	1s	10kHz	10dB	//														



Description..... :	Shredding and Sterilization of Hazardous Waste, T-series
Trademark .....	SCHLUMBOHM
Model and/or type reference.... :	Truster T50
Manufacturer .....	SMI Medical S.r.l.
Applicant .....	SMI MEDICAL S.R.L
Test Location .....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy
Test Engineer..... :	Francesco Barbierato
Method used..... :	EN 55011
Operating condition .....	OM#1
Phase .....	N
Notes .....	Peak and Average detector used for preview test. The investigated conductor presents some spikes that are not to be considered because they are due to the activation of the solenoid valve.



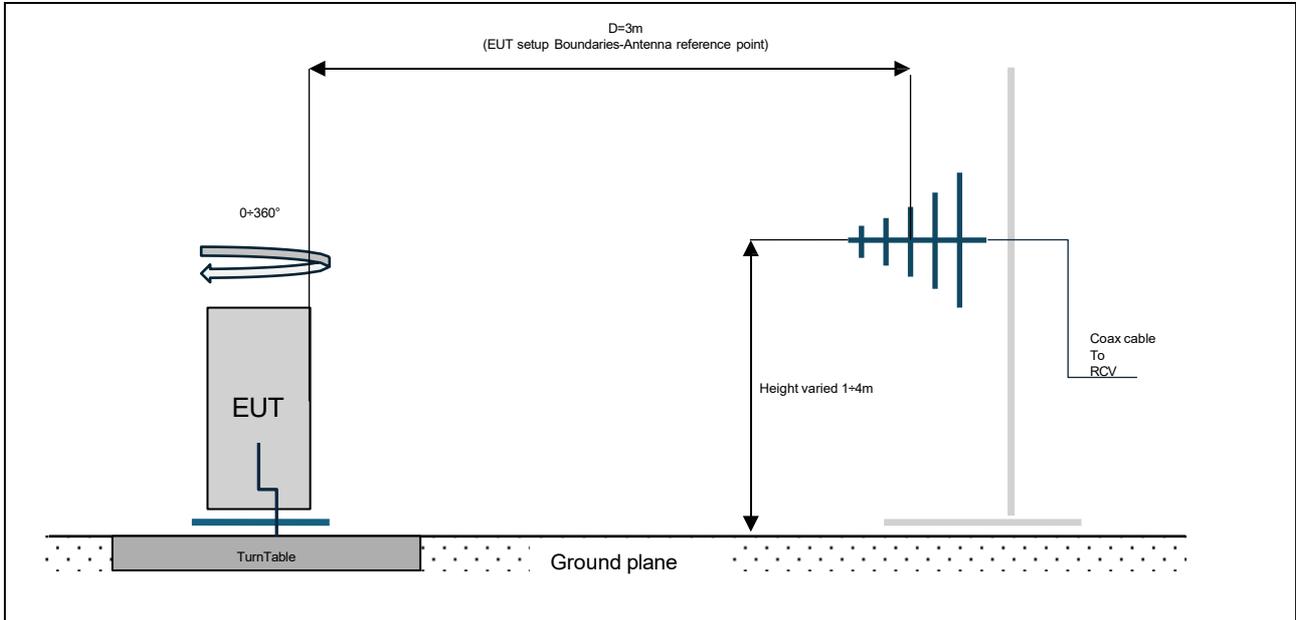
Legenda..... :	<ul style="list-style-type: none"> <li><span style="color: red;">—</span> QP Limit Line</li> <li><span style="color: blue;">—</span> AV Limit Line</li> <li><span style="color: green;">—</span> Measured Value MaxPeak</li> <li><span style="color: magenta;">—</span> Measured Value Average</li> </ul>
----------------	---

Receiver settings .....	<table border="1"> <thead> <tr> <th>Frequency range</th> <th>Detector</th> <th>Dwell time</th> <th>Res.BW</th> <th>Att.</th> <th>Preamp</th> </tr> </thead> <tbody> <tr> <td>0.15+30MHz</td> <td>Peak Average</td> <td>20ms</td> <td>10kHz</td> <td>10dB</td> <td>//</td> </tr> <tr> <td>0.15+30MHz</td> <td>Quasi-Peak(Final) Average(Final)</td> <td>1s</td> <td>10kHz</td> <td>10dB</td> <td>//</td> </tr> </tbody> </table>	Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp	0.15+30MHz	Peak Average	20ms	10kHz	10dB	//	0.15+30MHz	Quasi-Peak(Final) Average(Final)	1s	10kHz	10dB	//
Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp														
0.15+30MHz	Peak Average	20ms	10kHz	10dB	//														
0.15+30MHz	Quasi-Peak(Final) Average(Final)	1s	10kHz	10dB	//														



## 5.2 Radiated emission

### 5.2.1 Test setup



<input checked="" type="checkbox"/>	Test setup according reference standard has been realized
<input type="checkbox"/>	Test setup according reference standard has been realized with following deviations

### 5.2.2 Test setup Pictures



### 5.2.3 Instruments used for the test

Internal N°	Description	Type/Model	Manufacturer	Serial N°
E015	Spectrum Analyzer	SSA3075X Plus	Siglent	SSA5PEAC5R0002
E008	BiLog Antenna	CBL 6111B	Chase	2167
ER01	N-N_8m	Sucoflex 404A_N-N_8m	Huber&Suhner	113

### 5.2.4 Software

Internal N°	Development company	Name	Version	Year
S002	TEKBOX DIGITAL SOLUTIONS	EMCView	9.06	2023

### 5.2.5 Accessories

Internal N°	Description	Type/Model	Manufacturer	Serial N°
--	--	--	--	--



**5.2.6 Test details**

Reference standard .....	EN 55011															
Tested by .....	Francesco Barbierato															
Test date .....	03/06/2024															
Test location.....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy															
Environmental conditions .....	<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Parameter</th> <th style="width: 30%;">Ref. Std.Limit</th> <th style="width: 30%;">Actual</th> </tr> </thead> <tbody> <tr> <td>Temperature (°C)</td> <td>--(15÷35)</td> <td>23</td> </tr> <tr> <td>Humidity (% rh)</td> <td>--(30÷60)</td> <td>40</td> </tr> </tbody> </table>		Parameter	Ref. Std.Limit	Actual	Temperature (°C)	--(15÷35)	23	Humidity (% rh)	--(30÷60)	40					
Parameter	Ref. Std.Limit	Actual														
Temperature (°C)	--(15÷35)	23														
Humidity (% rh)	--(30÷60)	40														
EUT Setup Type .....	Floor standing															
Test method .....	OATS															
Port(s) .....	P#1_Enclosure															
Antenna position .....	Distance=3m, Height varied between 1 and 4m															
Antenna polarization .....	Horizontal and Vertical															
EUT orientation.....	Front, rear, left, right sides															
Frequency Band .....	30÷1000MHz															
Limits .....	<p><b>EN 55011, Class A, Group 1, &gt;20kVA</b></p> <table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width: 30%;">Frequency Band</th> <th colspan="2" style="text-align: center;">Limit</th> </tr> <tr> <th colspan="2" style="text-align: center;">Quasi Peak detector</th> </tr> <tr> <th style="text-align: center;">MHz</th> <th colspan="2" style="text-align: center;">dB(µV/m)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">30÷230</td> <td colspan="2" style="text-align: center;">60</td> </tr> <tr> <td style="text-align: center;">230÷1000</td> <td colspan="2" style="text-align: center;">60</td> </tr> </tbody> </table> <p><i>Limits for a measurement distance of 3m</i></p>		Frequency Band	Limit		Quasi Peak detector		MHz	dB(µV/m)		30÷230	60		230÷1000	60	
Frequency Band	Limit															
	Quasi Peak detector															
MHz	dB(µV/m)															
30÷230	60															
230÷1000	60															
Operating Mode(s).....	OM#1	Power ON, completely Operative														
	OM#2															
	OM#3															
	OM#4															
	OM#5															
Notes .....	None															

**5.2.7 Test result**

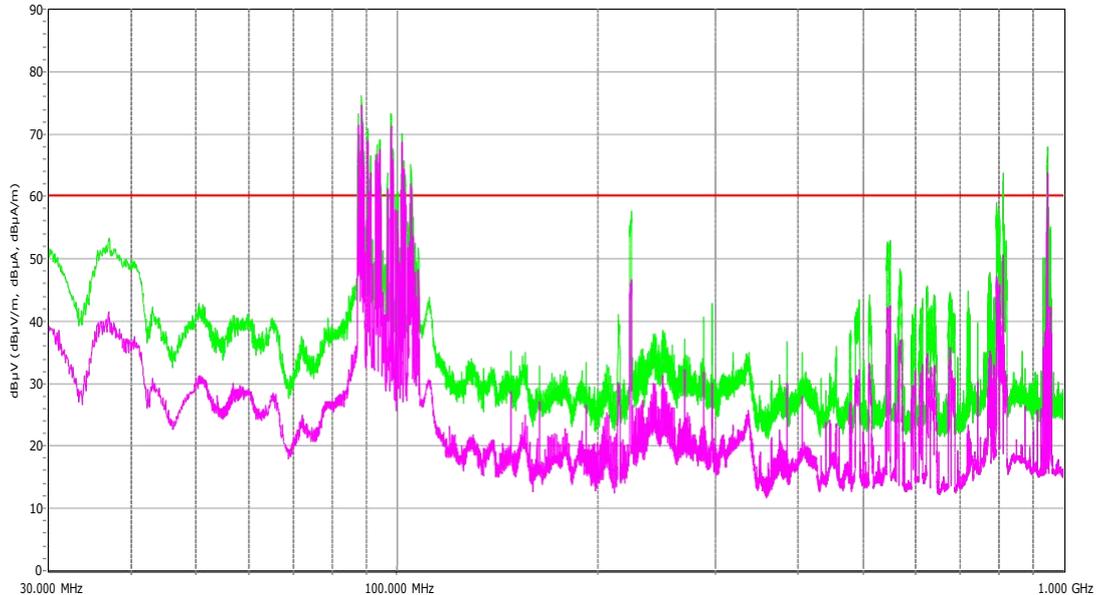
	OM#1
Equipment does COMPLY the requirements of this section	<input checked="" type="checkbox"/>
Equipment does NOT COMPLY this section	<input type="checkbox"/>



5.2.8 Test data

5.2.8.1 Graphics

Description.....	: Shredding and Sterilization of Hazardous Waste, T-series
Trademark .....	: SCHLUMBOHM
Model and/or type reference....	: Truster T50
Manufacturer .....	: SMI Medical S.r.l.
Applicant .....	: SMI MEDICAL S.R.L
Test Location .....	: Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy
Test Engineer.....	: Francesco Barbierato
Method used .....	: EN 55011
Operating condition .....	: Noise measurement
Polarization .....	: Horizontal
Notes .....	: Peak and Average detector, Front Side



Legenda.....

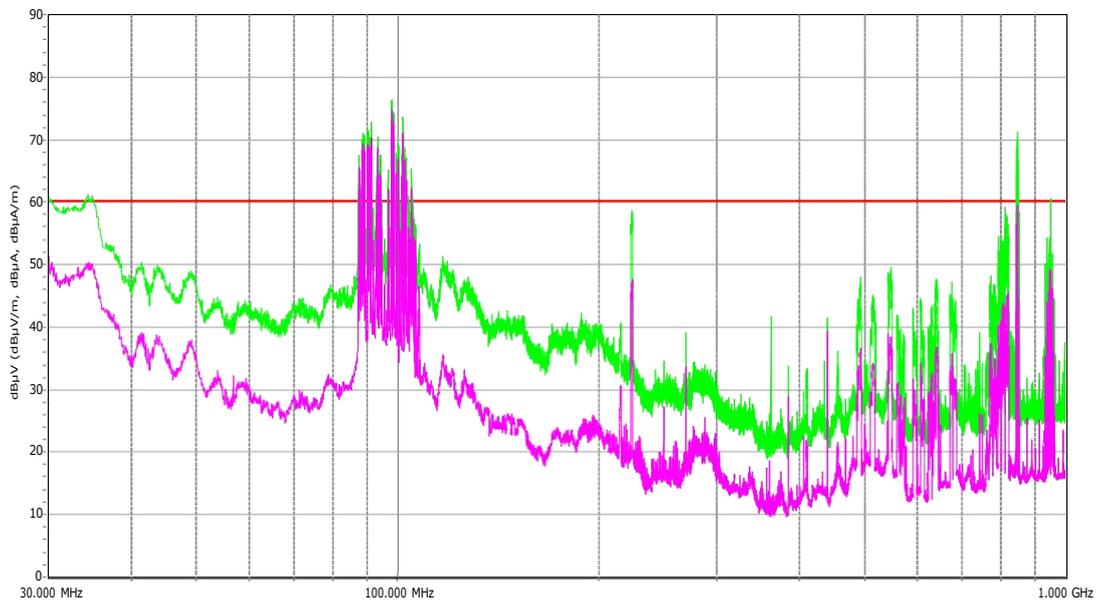
- QP Limit Line
- Measured Value
- Measured Value Average
- MaxPeak

Receiver settings .....

Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp
30÷1000MHz	Peak	20ms	120kHz	0dB	10dB
30÷1000MHz	Quasi-Peak(Final)	1s	120kHz	0dB	10dB



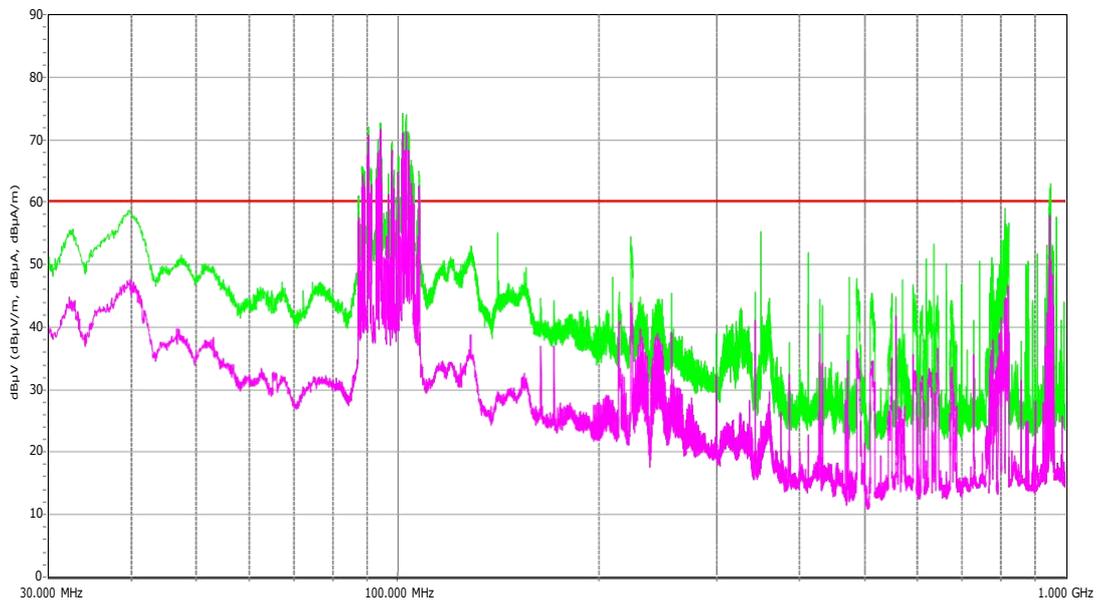
Description..... :	Shredding and Sterilization of Hazardous Waste, T-series
Trademark .....	SCHLUMBOHM
Model and/or type reference.... :	Truster T50
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Applicant .....	SMI MEDICAL S.R.L
Test Location .....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy
Test Engineer..... :	Francesco Barbierato
Method used..... :	EN 55011
Operating condition .....	Noise measurement
Polarization .....	Vertical
Notes .....	Peak and Average detector, Front Side



Legenda..... :	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <span style="color: red; font-weight: bold;">—</span> QP Limit Line         </div> <div style="text-align: center;"> <span style="color: green; font-weight: bold;">—</span> Measured Value MaxPeak         </div> <div style="text-align: center;"> <span style="color: magenta; font-weight: bold;">—</span> Measured Value Average         </div> </div>																		
Receiver settings .....	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Frequency range</th> <th>Detector</th> <th>Dwell time</th> <th>Res.BW</th> <th>Att.</th> <th>Preamp</th> </tr> </thead> <tbody> <tr> <td>30÷1000MHz</td> <td>Peak</td> <td>20ms</td> <td>120kHz</td> <td>0dB</td> <td>10dB</td> </tr> <tr> <td>30÷1000MHz</td> <td>Quasi-Peak(Final)</td> <td>1s</td> <td>120kHz</td> <td>0dB</td> <td>10dB</td> </tr> </tbody> </table>	Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp	30÷1000MHz	Peak	20ms	120kHz	0dB	10dB	30÷1000MHz	Quasi-Peak(Final)	1s	120kHz	0dB	10dB
Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp														
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30÷1000MHz	Quasi-Peak(Final)	1s	120kHz	0dB	10dB														



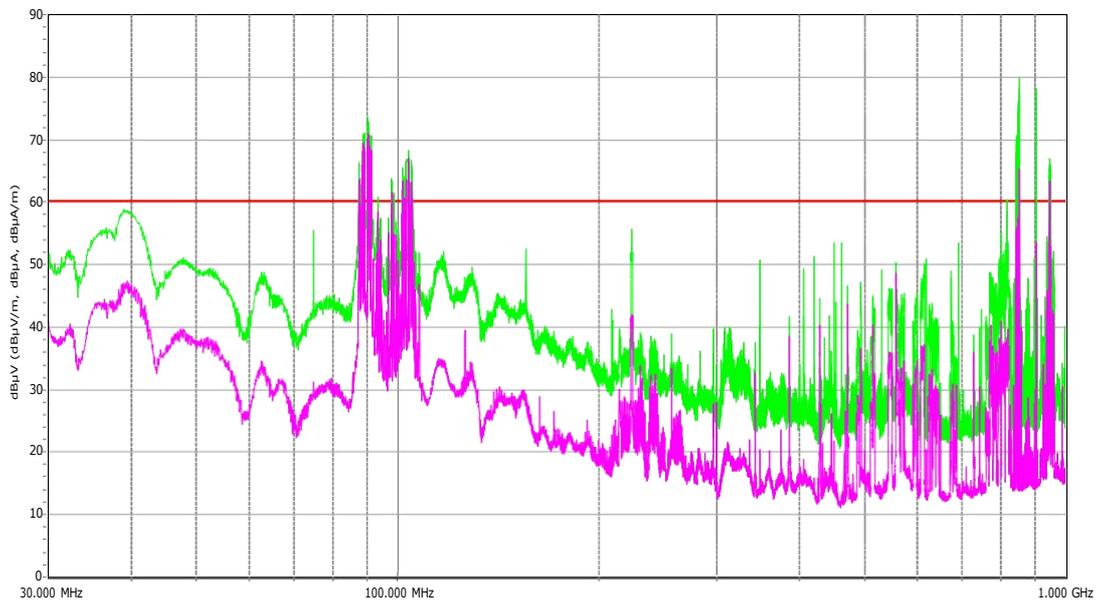
Description..... :	Shredding and Sterilization of Hazardous Waste, T-series
Trademark .....	SCHLUMBOHM
Model and/or type reference.... :	Truster T50
Manufacturer .....	SMI Medical S.r.l.
Applicant .....	SMI MEDICAL S.R.L
Test Location .....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy
Test Engineer..... :	Francesco Barbierato
Method used..... :	EN 55011
Operating condition .....	OM#1
Polarization .....	Horizontal
Notes .....	Peak and Average detector, Front Side



Legenda..... :	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <span style="color: red;">—</span> QP Limit Line  <span style="color: green;">—</span> Measured Value MaxPeak         </div> <div style="text-align: center;"> <span style="color: magenta;">—</span> Measured Value Average         </div> </div>																		
Receiver settings .....	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Frequency range</th> <th>Detector</th> <th>Dwell time</th> <th>Res.BW</th> <th>Att.</th> <th>Preamp</th> </tr> </thead> <tbody> <tr> <td>30÷1000MHz</td> <td>Peak</td> <td>20ms</td> <td>120kHz</td> <td>0dB</td> <td>10dB</td> </tr> <tr> <td>30÷1000MHz</td> <td>Quasi-Peak(Final)</td> <td>1s</td> <td>120kHz</td> <td>0dB</td> <td>10dB</td> </tr> </tbody> </table>	Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp	30÷1000MHz	Peak	20ms	120kHz	0dB	10dB	30÷1000MHz	Quasi-Peak(Final)	1s	120kHz	0dB	10dB
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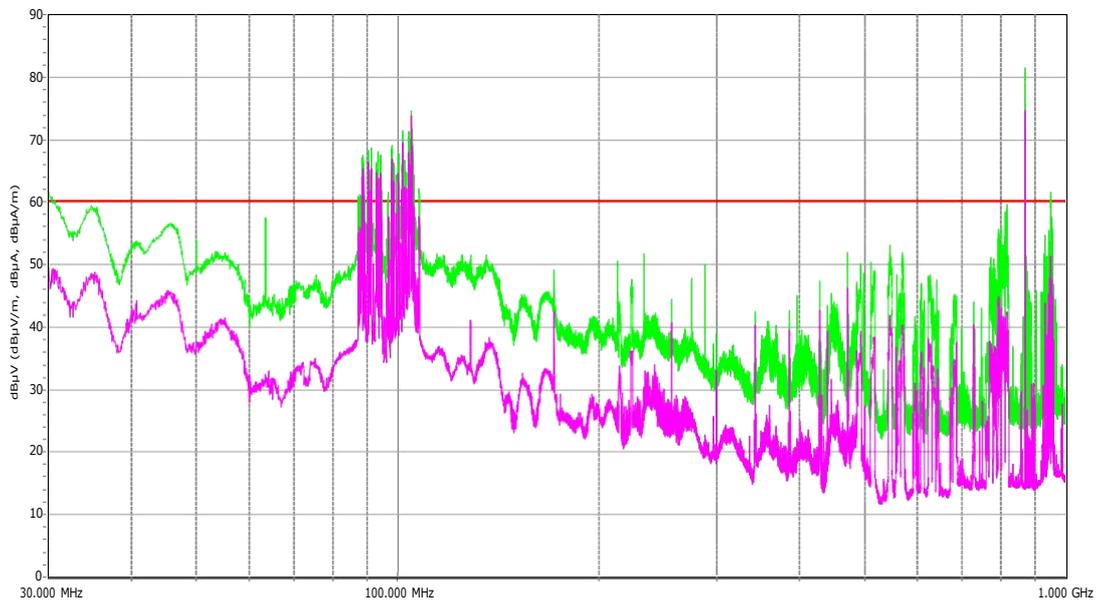
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Model and/or type reference.... :	Truster T50
Manufacturer .....	SMI Medical S.r.l.
Applicant .....	SMI MEDICAL S.R.L
Test Location .....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy
Test Engineer..... :	Francesco Barbierato
Method used..... :	EN 55011
Operating condition .....	OM#1
Polarization .....	Vertical
Notes .....	Peak and Average detector, Front Side



Legenda..... :	<p>— QP Limit Line</p> <p>— Measured Value MaxPeak</p> <p>— Measured Value Average</p>																		
Receiver settings .....	<table border="1"> <thead> <tr> <th>Frequency range</th> <th>Detector</th> <th>Dwell time</th> <th>Res.BW</th> <th>Att.</th> <th>Preamp</th> </tr> </thead> <tbody> <tr> <td>30÷1000MHz</td> <td>Peak</td> <td>20ms</td> <td>120kHz</td> <td>0dB</td> <td>10dB</td> </tr> <tr> <td>30÷1000MHz</td> <td>Quasi-Peak(Final)</td> <td>1s</td> <td>120kHz</td> <td>0dB</td> <td>10dB</td> </tr> </tbody> </table>	Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp	30÷1000MHz	Peak	20ms	120kHz	0dB	10dB	30÷1000MHz	Quasi-Peak(Final)	1s	120kHz	0dB	10dB
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30÷1000MHz	Quasi-Peak(Final)	1s	120kHz	0dB	10dB														



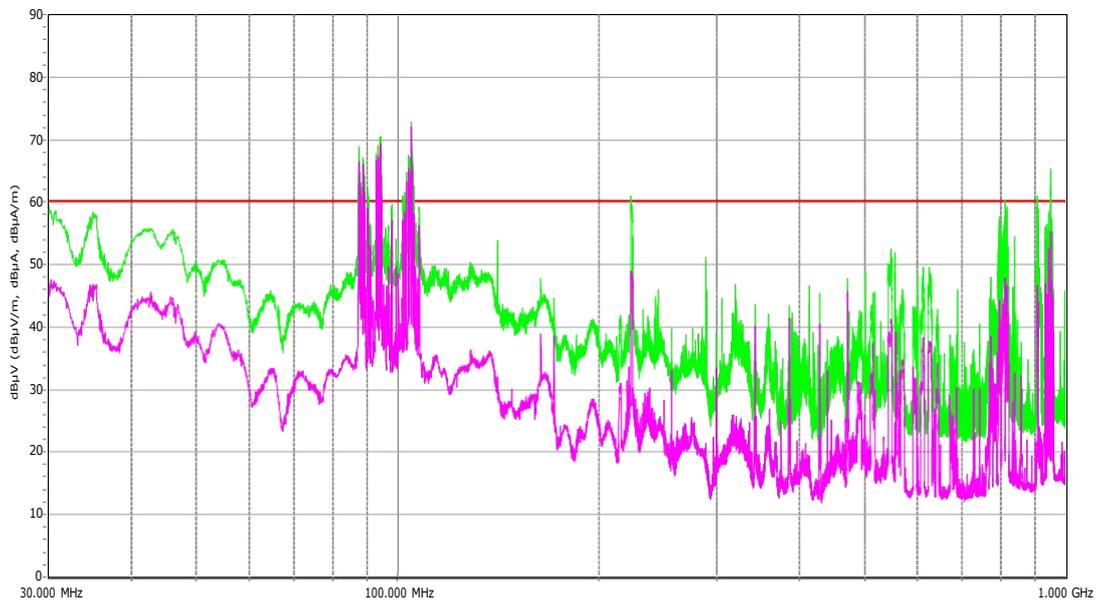
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Trademark .....	SCHLUMBOHM
Model and/or type reference.... :	Truster T50
Manufacturer .....	SMI Medical S.r.l.
Applicant .....	SMI MEDICAL S.R.L
Test Location .....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy
Test Engineer..... :	Francesco Barbierato
Method used..... :	EN 55011
Operating condition .....	OM#1
Polarization .....	Horizontal
Notes .....	Peak and Average detector, Rear Side



Legenda..... :	<div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;"> <span style="color: red; font-weight: bold;">—</span> QP Limit Line         </div> <div style="text-align: center;"> <span style="color: green; font-weight: bold;">—</span> Measured Value MaxPeak         </div> <div style="text-align: center;"> <span style="color: magenta; font-weight: bold;">—</span> Measured Value Average         </div> </div>																		
Receiver settings .....	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Frequency range</th> <th>Detector</th> <th>Dwell time</th> <th>Res.BW</th> <th>Att.</th> <th>Preamp</th> </tr> </thead> <tbody> <tr> <td>30÷1000MHz</td> <td>Peak</td> <td>20ms</td> <td>120kHz</td> <td>0dB</td> <td>10dB</td> </tr> <tr> <td>30÷1000MHz</td> <td>Quasi-Peak(Final)</td> <td>1s</td> <td>120kHz</td> <td>0dB</td> <td>10dB</td> </tr> </tbody> </table>	Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp	30÷1000MHz	Peak	20ms	120kHz	0dB	10dB	30÷1000MHz	Quasi-Peak(Final)	1s	120kHz	0dB	10dB
Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp														
30÷1000MHz	Peak	20ms	120kHz	0dB	10dB														
30÷1000MHz	Quasi-Peak(Final)	1s	120kHz	0dB	10dB														



Description..... :	Shredding and Sterilization of Hazardous Waste, T-series
Trademark .....	SCHLUMBOHM
Model and/or type reference.... :	Truster T50
Manufacturer .....	SMI Medical S.r.l.
Applicant .....	SMI MEDICAL S.R.L
Test Location .....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy
Test Engineer..... :	Francesco Barbierato
Method used..... :	EN 55011
Operating condition .....	OM#1
Polarization .....	Vertical
Notes .....	Peak and Average detector, Rear Side

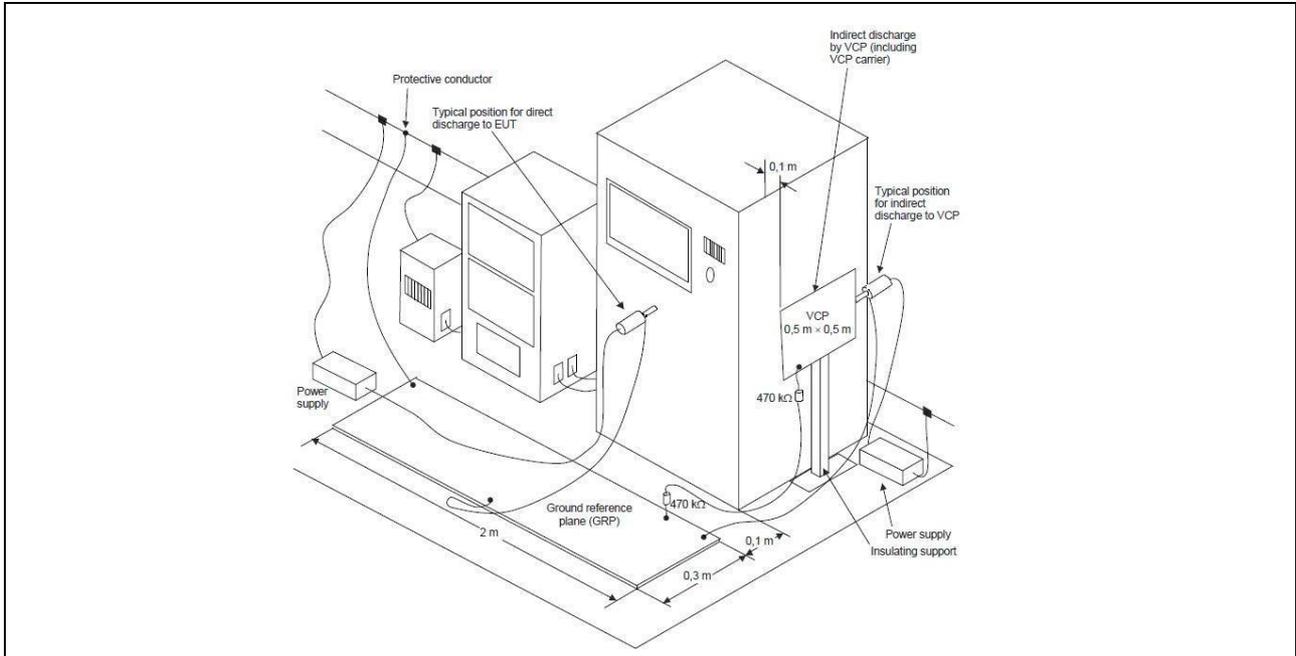


Legenda..... :	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <span style="color: red; font-weight: bold;">—</span> QP Limit Line         </div> <div style="text-align: center;"> <span style="color: green; font-weight: bold;">—</span> Measured Value MaxPeak         </div> <div style="text-align: center;"> <span style="color: magenta; font-weight: bold;">—</span> Measured Value Average         </div> </div>																		
Receiver settings .....	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Frequency range</th> <th>Detector</th> <th>Dwell time</th> <th>Res.BW</th> <th>Att.</th> <th>Preamp</th> </tr> </thead> <tbody> <tr> <td>30÷1000MHz</td> <td>Peak</td> <td>20ms</td> <td>120kHz</td> <td>0dB</td> <td>10dB</td> </tr> <tr> <td>30÷1000MHz</td> <td>Quasi-Peak(Final)</td> <td>1s</td> <td>120kHz</td> <td>0dB</td> <td>10dB</td> </tr> </tbody> </table>	Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp	30÷1000MHz	Peak	20ms	120kHz	0dB	10dB	30÷1000MHz	Quasi-Peak(Final)	1s	120kHz	0dB	10dB
Frequency range	Detector	Dwell time	Res.BW	Att.	Preamp														
30÷1000MHz	Peak	20ms	120kHz	0dB	10dB														
30÷1000MHz	Quasi-Peak(Final)	1s	120kHz	0dB	10dB														



### 5.3 Electrostatic discharge (ESD)

#### 5.3.1 Test setup



<input checked="" type="checkbox"/>	Test setup according reference standard has been realized
<input type="checkbox"/>	Test setup according reference standard has been realized with following deviations

#### 5.3.2 Test setup Pictures



### 5.3.3 Instruments used for the test

Internal N°	Description	Type/Model	Manufacturer	Serial N°
E028	ESD SIMULATOR SYSTEM	ESD NX30	EM TEST	23175
E029	ESD Discharge network (150pF-330Ohm)	RCN30 150-330	EM TEST	50488

### 5.3.4 Software

Internal N°	Development company	Name	Version	Year
--	--	--	--	--

### 5.3.5 Accessories

Internal N°	Description	Type/Model	Manufacturer	Serial N°
--	--	--	--	--



**5.3.6 Test details**

Reference standard .....	EN 61000-4-2														
Tested by .....	Francesco Barbierato														
Test date .....	03/06/2024														
Test location.....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy														
Environmental conditions .....	<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th style="width: 60%;">Parameter</th> <th style="width: 20%;">Ref. Std.Limit</th> <th style="width: 20%;">Actual</th> </tr> </thead> <tbody> <tr> <td>Temperature (°C)</td> <td>15÷35</td> <td>23</td> </tr> <tr> <td>Humidity (% rh)</td> <td>30÷60</td> <td>40</td> </tr> <tr> <td>Atmospheric pressure(hPa)</td> <td>860÷1060</td> <td>1014</td> </tr> </tbody> </table>			Parameter	Ref. Std.Limit	Actual	Temperature (°C)	15÷35	23	Humidity (% rh)	30÷60	40	Atmospheric pressure(hPa)	860÷1060	1014
Parameter	Ref. Std.Limit	Actual													
Temperature (°C)	15÷35	23													
Humidity (% rh)	30÷60	40													
Atmospheric pressure(hPa)	860÷1060	1014													
EUT Setup Type .....	Floor standing														
Test setup details .....	gounded floor-standing equipment														
Bleeding resistors .....	HCP, VCP														
Port(s) .....	P#1_Enclosure														
Discharge network .....	<input checked="" type="checkbox"/>	150pF / 330 Ω													
	<input type="checkbox"/>	330pF / 330 Ω													
	<input type="checkbox"/>	150pF / 2000 Ω													
	<input type="checkbox"/>	330pF / 2000 Ω													
Test Level .....	<input checked="" type="checkbox"/> ±2kV <input checked="" type="checkbox"/> ±4kV <input checked="" type="checkbox"/> ±6kV <input checked="" type="checkbox"/> ±8kV	Air discharge													
	<input type="checkbox"/> ±2kV <input checked="" type="checkbox"/> ±4kV <input type="checkbox"/> ±6kV <input type="checkbox"/> ±8kV	Contact discharge													
Discharge N° .....	10 (for each test point and polarity)														
Time between discharges.....	1 s														
Minimum required criterion .....	B														
Observed criterion .....	A_Normal operation during and after the test														
Operating Mode(s).....	OM#1   Power ON, completely Operative														
Notes .....	See 5.3.8 Test data for detailed test point description and observed EUT reactions														

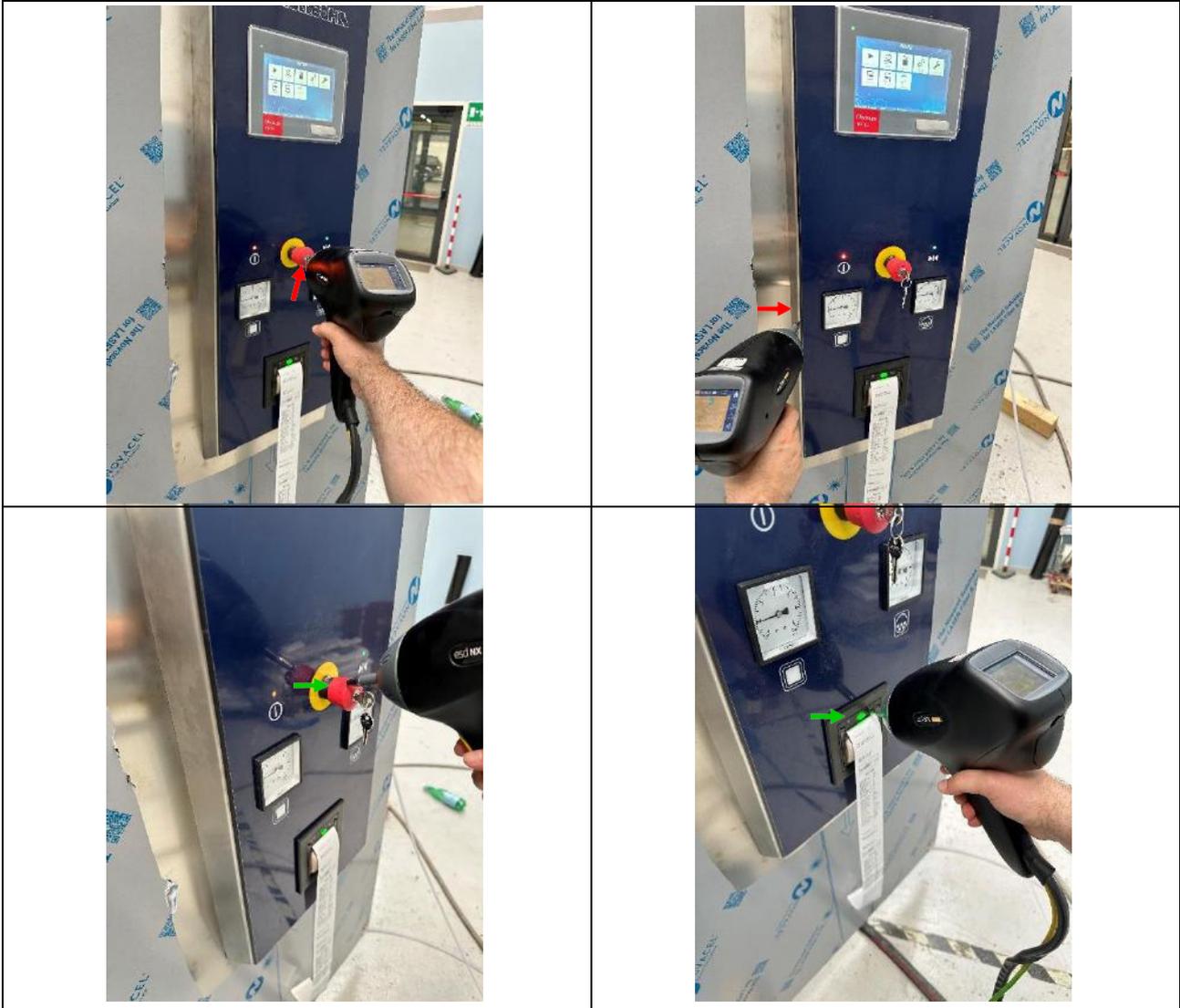
**5.3.7 Test result**

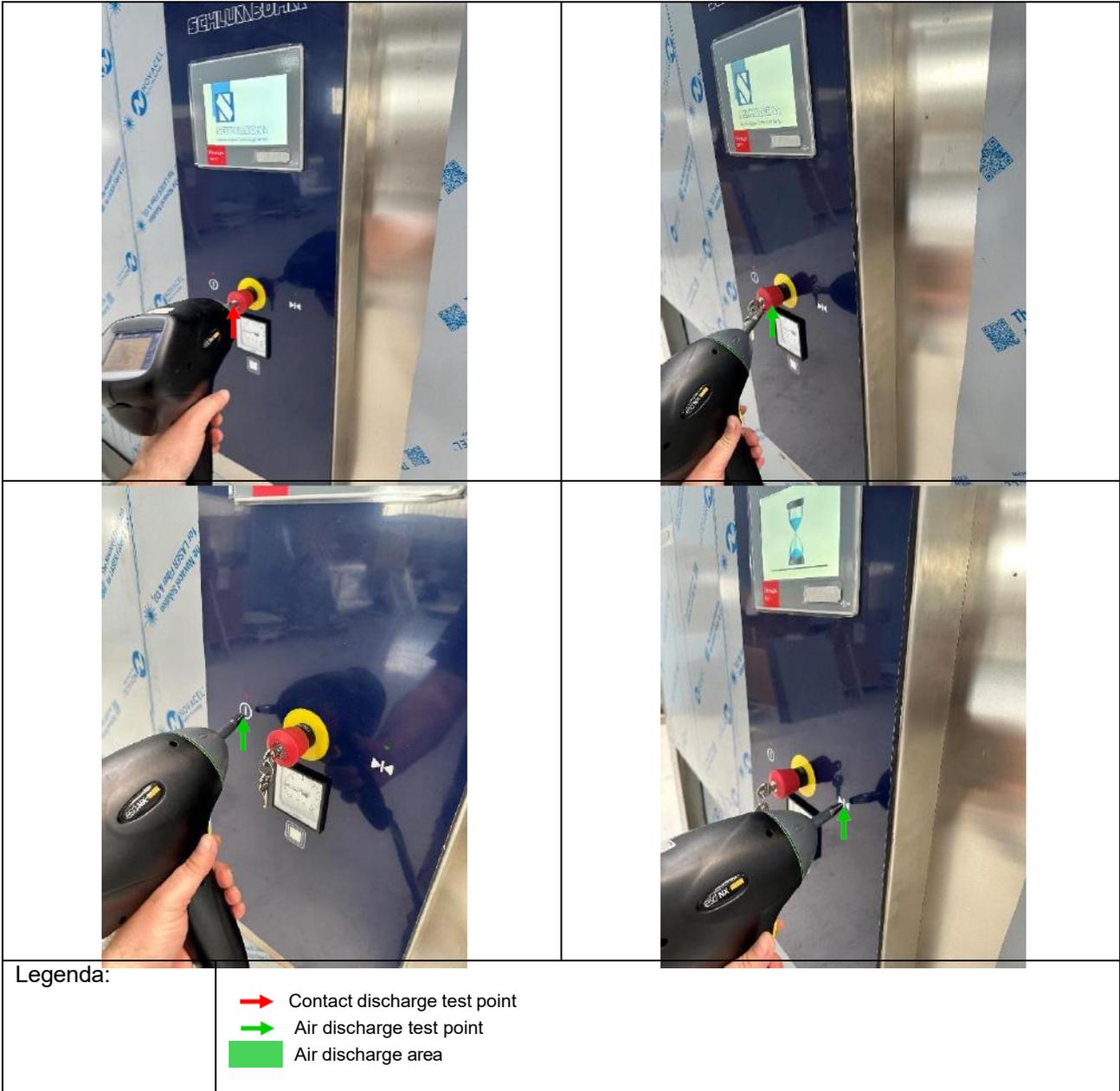
	OM#1
Equipment does COMPLY the requirements of this section	<input checked="" type="checkbox"/>
Equipment does NOT COMPLY this section	<input type="checkbox"/>



### 5.3.8 Test data

#### 5.3.8.1 Test point identification





**5.3.8.2 Tables**

ESD									
Contact discharges									
Polarity	Level	Method	Discharge Network	Discharge number	Notes	Performed	Required criterion	Observed criterion	Sequence
+	4	Contact	150pF/330Ω	10	-	X	A	A	1
-	4	Contact	150pF/330Ω	10	-	X	A	A	2
Air discharges									
Polarity	Level	Method	Discharge Network	Discharge number	Notes	Performed	Required criterion	Observed criterion	Sequence
+	2	Air	150pF/330Ω	10	-	X	A	A	3
-	2	Air	150pF/330Ω	10	-	X	A	A	4
+	4	Air	150pF/330Ω	10	-	X	A	A	5
-	4	Air	150pF/330Ω	10	-	X	A	A	6
+	6	Air	150pF/330Ω	10	-	X	A	A	7
-	6	Air	150pF/330Ω	10	-	X	A	A	8
+	8	Air	150pF/330Ω	10	-	X	A	A	9
-	8	Air	150pF/330Ω	10	-	X	A	A	10

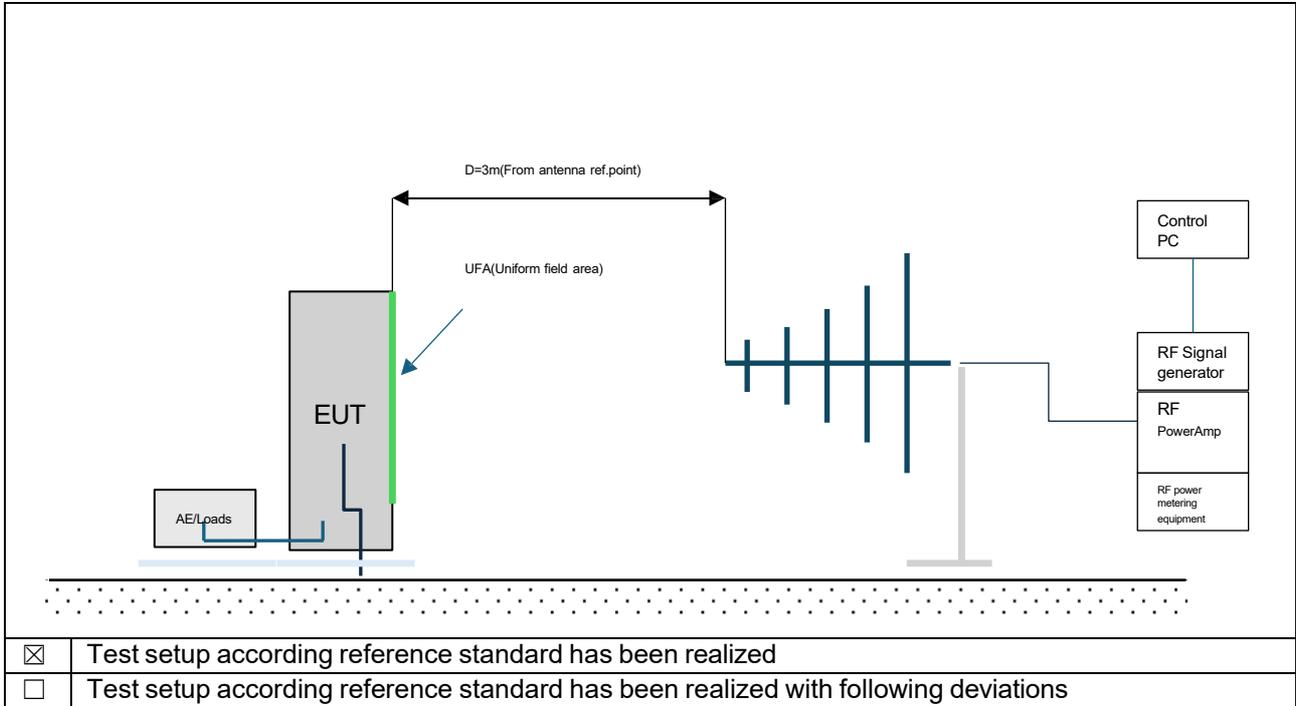
**5.3.8.3 Observed reaction description**

A	Normal operation during and after the test
B	//
C	//
D	//

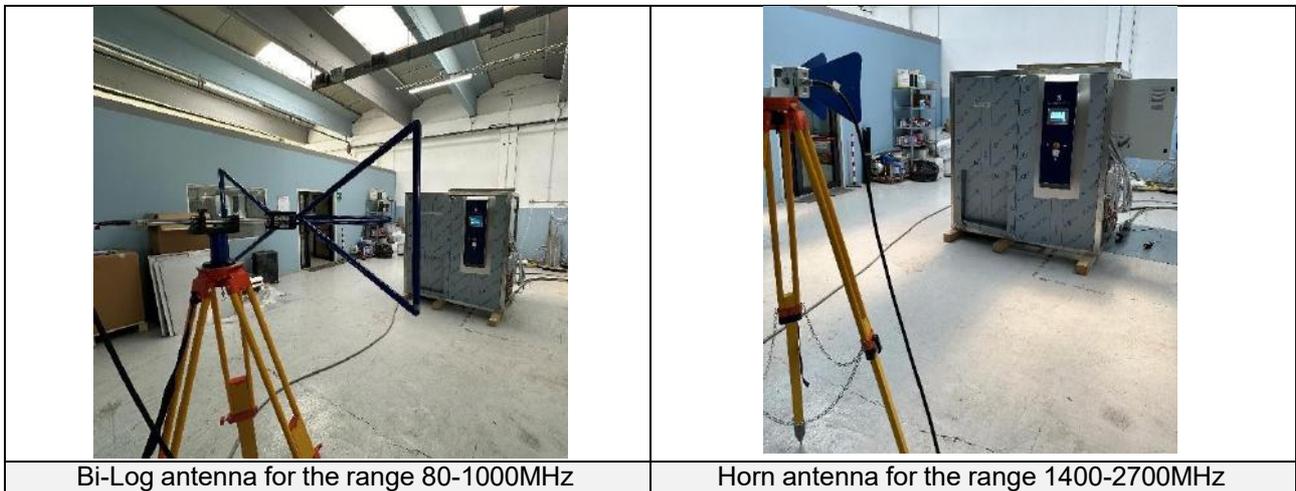


## 5.4 Electromagnetic field

### 5.4.1 Test setup



### 5.4.2 Test setup Pictures



### 5.4.3 Instruments used for the test

Internal N°	Description	Type/Model	Manufacturer	Serial N°
E041	Vector Signal Generator	SMCV100B	Rohde & Schwarz	103629
E008	BiLog Antenna	CBL 6111B	Chase	2167
E010	Horn Antenna	PowerLOG 70180	Aaronia	4525
E005	RF Power Amplifier	200W1000M7A	Amplifier Research	20240
E006	RF Power Amplifier	50S1G4A	Amplifier Research	300984
E025	Directional Coupler	3020A	Narda	30958
E026	Directional Coupler	3202B-20	Narda	5985-820-6420-03040
E034	Power Sensor 8kHz – 6GHz	NRP6AN	Rohde & Schwarz	101928
E035	Power Sensor 8kHz – 6GHz	NRP6AN	Rohde & Schwarz	101929
ER01	N-N_8m	Sucoflex 404A_N-N_8m	Huber&Suhner	113

### 5.4.4 Software

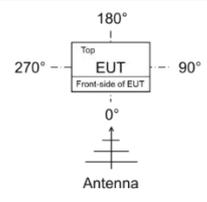
Internal N°	Development company	Name	Version	Year
S004	Inlab S.r.l.	InLab_IIS	1.0	2023

### 5.4.5 Accessories

Internal N°	Description	Type/Model	Manufacturer	Serial N°
--	--	--	--	--



### 5.4.6 Test details

Reference standard .....	EN 61000-4-3										
Tested by .....	Francesco Barbierato										
Test date .....	03/06/2024										
Test location.....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy										
Environmental conditions .....	<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th>Parameter</th> <th>Ref. Std.Limit</th> <th>Actual</th> </tr> </thead> <tbody> <tr> <td>Temperature (°C)</td> <td>--(15÷35)</td> <td>23</td> </tr> <tr> <td>Humidity (% rh)</td> <td>--(30÷60)</td> <td>40</td> </tr> </tbody> </table>		Parameter	Ref. Std.Limit	Actual	Temperature (°C)	--(15÷35)	23	Humidity (% rh)	--(30÷60)	40
Parameter	Ref. Std.Limit	Actual									
Temperature (°C)	--(15÷35)	23									
Humidity (% rh)	--(30÷60)	40									
EUT Setup Type .....	Floor standing										
Port(s) .....	P#1_Enclosure										
Test method .....	Substitution(Forward power)										
Frequency band.....	80MHz÷2.7GHz										
Frequency step.....	1%										
Test Level .....	10V/m	80÷1000MHz									
	3V/m	(1000)1400÷2700MHz									
Modulation .....	AM, frequency=1kHz, depth=80%										
Polarization .....	Horizontal and Vertical										
Dwell time .....	2s										
Uniform field area size .....	1.5 m x 1.5 m										
DUT Exposed side(s).....	<input checked="" type="checkbox"/> 0° (front) <input type="checkbox"/> 90° (left) <input checked="" type="checkbox"/> 180° (rear) <input type="checkbox"/> 270° (right) <input type="checkbox"/> Top side <input type="checkbox"/> Bottom Side										
Reason for not exposing a side .....	<i>Side not checked were considered not relevant from the EMC point of view</i>										
Minimum required criterion .....	A										
Observed criterion .....	A_Normal operation during and after the test										
Operating Mode(s).....	OM#1	Power ON, completely Operative									
Notes .....											

### 5.4.7 Test result

	OM#1
Equipment does COMPLY the requirements of this section	<input checked="" type="checkbox"/>
Equipment does NOT COMPLY this section	<input type="checkbox"/>



## 5.4.8 Test data

### 5.4.8.1 Tables

Band MHz	Level V/m	Polarization (H/V)	Modulation	Operating condition	Exposed side	Required Criterion	Observed Criterion	Notes
80-1000	10	H	AM, d=80%, f=1kHz	OM#1	0°(Front)	A	A	
80-1000	10	V	AM, d=80%, f=1kHz	OM#1	0°(Front)	A	A	
1400-2000	3	H	AM, d=80%, f=1kHz	OM#1	0°(Front)	A	A	
1400-2000	3	V	AM, d=80%, f=1kHz	OM#1	0°(Front)	A	A	
2000-2700	3	H	AM, d=80%, f=1kHz	OM#1	0°(Front)	A	A	
2000-2700	3	V	AM, d=80%, f=1kHz	OM#1	0°(Front)	A	A	
Band MHz	Level V/m	Polarization (H/V)	Modulation	Operating condition	Exposed side	Required Criterion	Observed Criterion	Notes
80-1000	10	H	AM, d=80%, f=1kHz	OM#1	180°(Rear)	A	A	
80-1000	10	V	AM, d=80%, f=1kHz	OM#1	180°(Rear)	A	A	
1400-2700	3	H	AM, d=80%, f=1kHz	OM#1	180°(Rear)	A	A	
1400-2700	3	V	AM, d=80%, f=1kHz	OM#1	180°(Rear)	A	A	
2000-2700	3	H	AM, d=80%, f=1kHz	OM#1	180°(Rear)	A	A	
2000-2700	3	V	AM, d=80%, f=1kHz	OM#1	180°(Rear)	A	A	

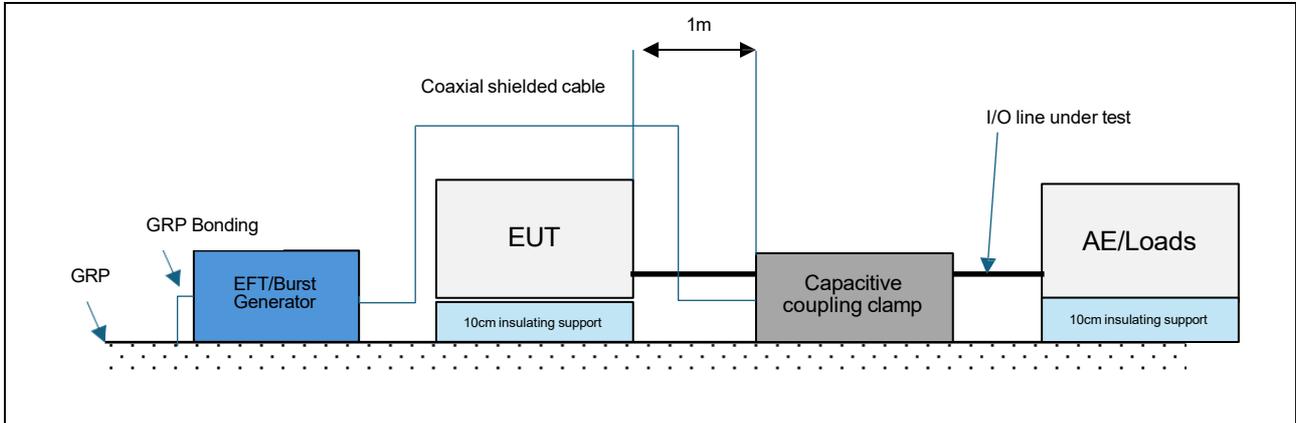
### 5.4.8.2 Observed reaction description

A	Normal operation during and after the test
B	//
C	//
D	//



## 5.5 Fast transients, Burst

### 5.5.1 Test setup



<input checked="" type="checkbox"/>	Test setup according reference standard has been realized
<input type="checkbox"/>	Test setup according reference standard has been realized with following deviations

### 5.5.2 Test setup Pictures



### 5.5.3 Instruments used for the test

Internal N°	Description	Type/Model	Manufacturer	Serial N°
E012	EFT/Burst Clamp	CCC-FTB	EM TEST	/
E055	Fast transient generator	EFT 500	EM Test	0795-34

### 5.5.4 Software

Internal N°	Development company	Name	Version	Year
S005	Inlab S.r.l.	IEC.Master	1.0	2024

### 5.5.5 Accessories

Internal N°	Description	Type/Model	Manufacturer	Serial N°
--	--	--	--	--



**5.5.6 Test details**

Reference standard .....	EN 61000-4-4											
Tested by .....	Francesco Barbierato											
Test date .....	03/06/2024											
Test location.....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy											
Environmental conditions .....	<table border="1"> <thead> <tr> <th>Parameter</th> <th>Ref. Std.Limit</th> <th>Actual</th> </tr> </thead> <tbody> <tr> <td>Temperature (°C)</td> <td>--(15+35)</td> <td>23</td> </tr> <tr> <td>Humidity (% rh)</td> <td>--(30+60)</td> <td>40</td> </tr> </tbody> </table>			Parameter	Ref. Std.Limit	Actual	Temperature (°C)	--(15+35)	23	Humidity (% rh)	--(30+60)	40
Parameter	Ref. Std.Limit	Actual										
Temperature (°C)	--(15+35)	23										
Humidity (% rh)	--(30+60)	40										
EUT Setup Type .....	Floor standing											
Test setup details .....	EUT+AE on 10cm insulating support over GRP, Power supply cable length=1m (Floor-standing)											
Port(s) .....	P#2_ TP_AC_IN1_400VAC											
Pulse parameters .....	frequency=5kHz, duration=15ms, burst period=300ms											
Pulse level, polarity, coupling..	See table below											
Minimum required criterion .....	B											
Observed criterion .....	A_Normal operation during and after the test											
Operating Mode(s).....	OM#1   Power ON, completely Operative											
Notes .....												

Port	Coupling	Level	Operating mode	Required criterion	Observed criterion	Pass	Fail
P#2_ TP_AC_IN1_400VAC	Capacitive coupling clamp	±1kV	OM#1	B	A	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**5.5.7 Test result**

	OM#1
Equipment does COMPLY the requirements of this section	<input checked="" type="checkbox"/>
Equipment does NOT COMPLY this section	<input type="checkbox"/>



### 5.5.8 Test data

<b>Test laboratory:</b>	Inlab S.r.l.		
<b>Operator:</b>	F.Barbierato		
<b>EUT Code:</b>	073-24_2	<b>Inventory Code:</b>	073-24_2
<b>Customer:</b>	SMI MEDICAL S.R.L	<b>Customer Code:</b>	073-24
<b>Manufacturer:</b>	SMI Medical S.r.l.		
<b>EUT Description:</b>	Shredding and Sterilization of Hazardous Waste, T-series		
<b>EUT Model:</b>	Truster T50		
<b>EUT Serial N°:</b>	SMI-01364		
<b>EUT Operating state:</b>	OM#1		
<b>Reference standard:</b>	EN 61000-4-4		
<b>Test Comments:</b>	P#2_TP_AC_IN1_400VAC		

<b>Test start</b>	03/06/2024	<b>Test end</b>	31/05/2024
-------------------	------------	-----------------	------------

<b>Temperature</b>	22,5°C
<b>Humidity</b>	52% rh

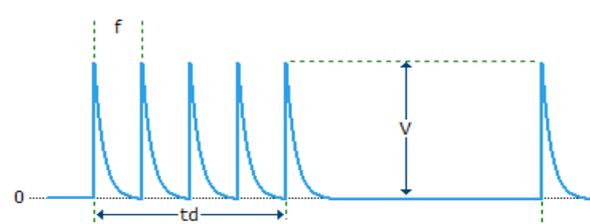
## Test result PASS

### Instruments used

Code	Description	Model	Manufacturer	Serial N
E001	Ultra compact simulator	UCS 500-M4	EM Test A.G.	001243
E012	CapacitiveCouplingClamp	CCC-FTB	EM Test A.G.	E012

### Test settings

Test mode	Burst
V	1000 V
f	5,0 kHz
td	15,0 ms
tr	300,0 ms
Polarities	+,-
DurationTime	60 s
PauseTime	2 s
Couplings	50 Ohm
CouplingNetwork	INT



### Test results

V_Set	f_Set	td_Set	tr_Set	Couplings_Set	PulseStart	PulseStop
+1000 V	5,0 kHz	15,0 ms	300,0 ms	50Ohm	03/06/2024	03/06/2024
-1000 V	5,0 kHz	15,0 ms	300,0 ms	50Ohm	03/06/2024	03/06/2024

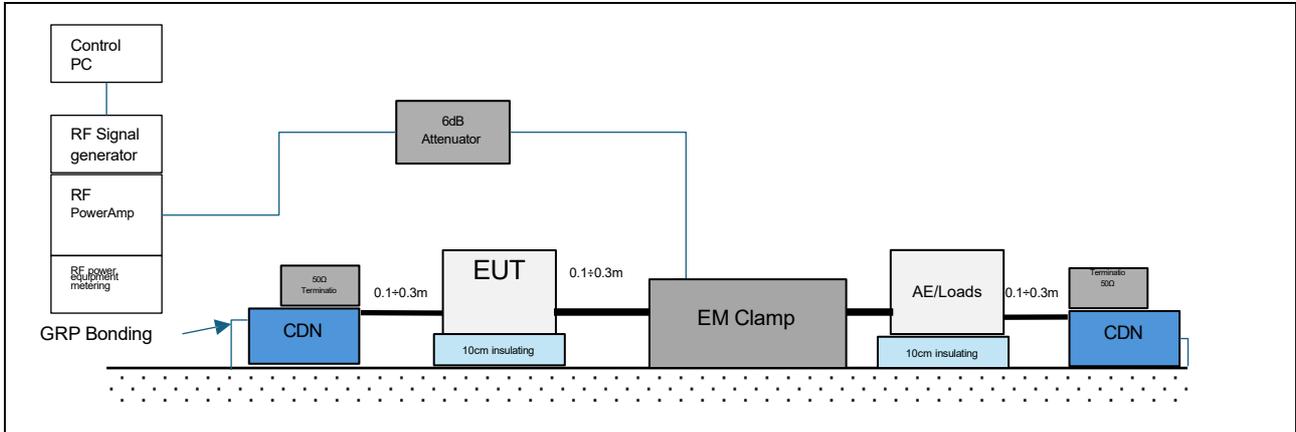
### 5.5.8.1 Observed reaction description

A	Normal operation during and after the test
B	//
C	//
D	//



## 5.6 Radio frequency common mode

### 5.6.1 Test setup



<input checked="" type="checkbox"/>	Test setup according reference standard has been realized
<input type="checkbox"/>	Test setup according reference standard has been realized with following deviations

### 5.6.2 Test setup Pictures



### 5.6.3 Instruments used for the test

Internal N°	Description	Type/Model	Manufacturer	Serial N°
E041	Vector Signal Generator	SMCV100B	Rohde & Schwarz	103629
E007	RF Power Amplifier	100A250A	Amplifier Research	464206
E039	RF attenuator	100W6dB DC-3GHz	BECEN	X001A41QVF
E034	Power Sensor 8kHz – 6GHz	NRP6AN	Rohde & Schwarz	101928
E035	Power Sensor 8kHz – 6GHz	NRP6AN	Rohde & Schwarz	101929
E013	EM clamp	CLEM 6146	COM Power	16030007
ER01	N-N_8m	Sucoflex 404A_N-N_8m	Huber&Suhner	113

### 5.6.4 Software

Internal N°	Development company	Name	Version	Year
S004	Inlab S.r.l.	InLab_IIS	1.0	2023

### 5.6.5 Accessories

Internal N°	Description	Type/Model	Manufacturer	Serial N°
--	--	--	--	--



**5.6.6 Test details**

Reference standard .....	EN 61000-4-6											
Tested by .....	Francesco Barbierato											
Test date .....	03/06/2024											
Test location.....	Via Piemonte, 112 56035 Casciana Terme Lari (PI) - Italy											
Environmental conditions .....	<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th>Parameter</th> <th>Ref. Std.Limit</th> <th>Actual</th> </tr> </thead> <tbody> <tr> <td>Temperature (°C)</td> <td>--(15+35)</td> <td>23</td> </tr> <tr> <td>Humidity (% rh)</td> <td>--(30+60)</td> <td>40</td> </tr> </tbody> </table>			Parameter	Ref. Std.Limit	Actual	Temperature (°C)	--(15+35)	23	Humidity (% rh)	--(30+60)	40
Parameter	Ref. Std.Limit	Actual										
Temperature (°C)	--(15+35)	23										
Humidity (% rh)	--(30+60)	40										
EUT Setup Type .....	Floor standing											
Port(s) .....	P#2_TP_AC_IN1_400VAC											
Frequency band.....	0.15MHz+80MHz											
Frequency step.....	1%											
Test Level .....	3V	0.15MHz+80MHz										
Modulation .....	AM, frequency=1kHz, depth=80%											
Dwell time .....	2s											
Minimum required criterion .....	A											
Observed criterion .....	A_Normal operation during and after the test											
Operating Mode(s).....	OM#1	Power ON, completely Operative										
Notes .....												

Port	Coupling Mode	Terminated ports	Level	Operating mode	Required criterion	Observed criterion	Pass	Fail
P#2_ TP_AC_IN1_400VAC	EM Clamp	-	3V	OM#1	A	A	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**5.6.7 Test result**

	OM#1
Equipment does COMPLY the requirements of this section	<input checked="" type="checkbox"/>
Equipment does NOT COMPLY this section	<input type="checkbox"/>



### 5.6.8 Test data

Band MHz	Level V	Coupling Type	Ports	Modulation (AM, PM, CW)	Operating condition	Required Criterion	Observed Criterion	Notes
0.15-80	3	EM Clamp	AC power port	AM	OM#1	A	A	-

### 5.6.8.1 Observed reaction description

A	Normal operation during and after the test
B	//
C	//
D	//

## End of test report

*Test results are referred only to the sample tested. Sampling is on Appliant's charge and responsibility.  
 InLab S.r.l. it is not responsible for sampling, the test sample was provided by the Appliant and has been tested as received.  
 InLab S.r.l. declines responsibility for data from the Appliant that affects the validity of the results.  
 InLab S.r.l. assumes no responsibility for the truthfulness of the data provided by the Appliant, nor assumes the charge to verify it.  
 Any partial reproduction of this document should be authorised by InLab S.r.l.*





## Annex section

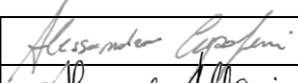
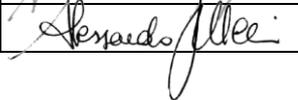
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Test Report issued under the responsibility of:



<b>TEST REPORT IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements</b>	
<b>Report Reference No.....:</b>	S.318.01_SAF104_B0.0
<b>Date of issue .....</b>	2024/07/23
<b>Total number of pages.....:</b>	42
<b>Testing Laboratory .....</b>	MEQUIPE S.r.l.
<b>Address .....</b>	Via XXV Aprile, 11 – 20097 San Donato Milanese (MI) ITALY
<b>Applicant’s name.....:</b>	SMI Medical S.r.l.
<b>Address .....</b>	Via Rinchiosa, 20C – 54033 Marina di Carrara (MS) ITALY
<b>Test specification:</b>	
<b>Standard .....</b>	IEC 61010-1:2010 + A1:2016
<b>Test procedure .....</b>	/
<b>Non-standard test method.....:</b>	/
<b>Test Report Form No.....:</b>	IEC61010_1L
<b>Test Report Form(s) Originator.....:</b>	MEQUIPE S.r.l.
<b>Master TRF .....</b>	Dated 2020-09
<b>Test item description .....</b>	Waste treatment device
<b>Trademark .....</b>	SCHLUMBOHM
<b>Manufacturer.....:</b>	SMI Medical S.r.l.
<b>Model/Type reference .....</b>	Truster T Series (tested model T.50.E)
<b>Ratings .....</b>	400 V, 50/60 Hz, 100 kVA
<b>General disclaimer:</b>	
The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing Testing Laboratory. The authenticity of this Test Report and its contents can be verified by contacting the Issuing Testing Laboratory, responsible for this Test Report.	

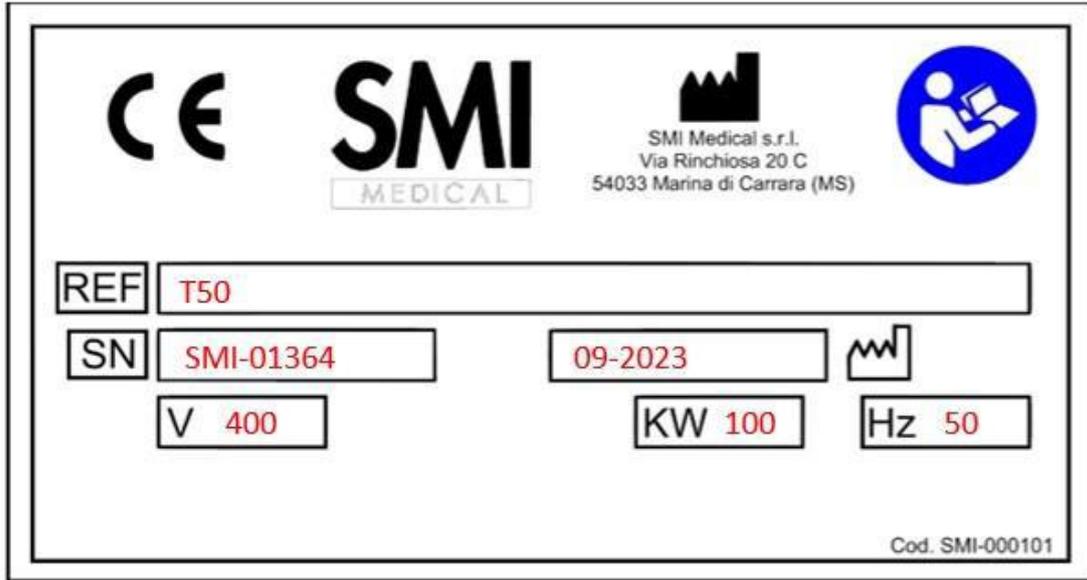
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
Testing Laboratory .....	MEQUIPE S.r.l.	
Testing location/ address .....	Via XXV Aprile, 11 – 20097 San Donato Milanese (MI) ITALY	
Tested by (name, function, signature) .....	A. Capoferri	
Approved by (name, function, signature).....	A. Melzi	

List of Attachments (including a total number of pages in each attachment)		
Document No.	Documents included / attached to this report (description)	Page No.
1	Test Equipment List	1
2	Photographic Report	6
3	Use and maintenance manual of medical waste treatment -Truster Rev. 1.0 date 2024/07/22	97
4	Truster series - Risk Assessment (file FT_TRUSTER_C07_ANALISYS_00) Rev. 00 date 2021/05/20	58
5	Baaske Medical type MI 1005 network isolator datasheet + UL Certificate of Compliance + Manufacturer's EU declaration of conformity	6
6	Mean Well NDR-120-12 SMPS unit datasheet + TUV Rheinland LGA Product Certificate of Compliance + Manufacturer's CE declaration of conformity	10
7	Mean Well NDR-240-24 SMPS unit datasheet + TUV Rheinland LGA Product Certificate of Compliance + Manufacturer's CE declaration of conformity	7

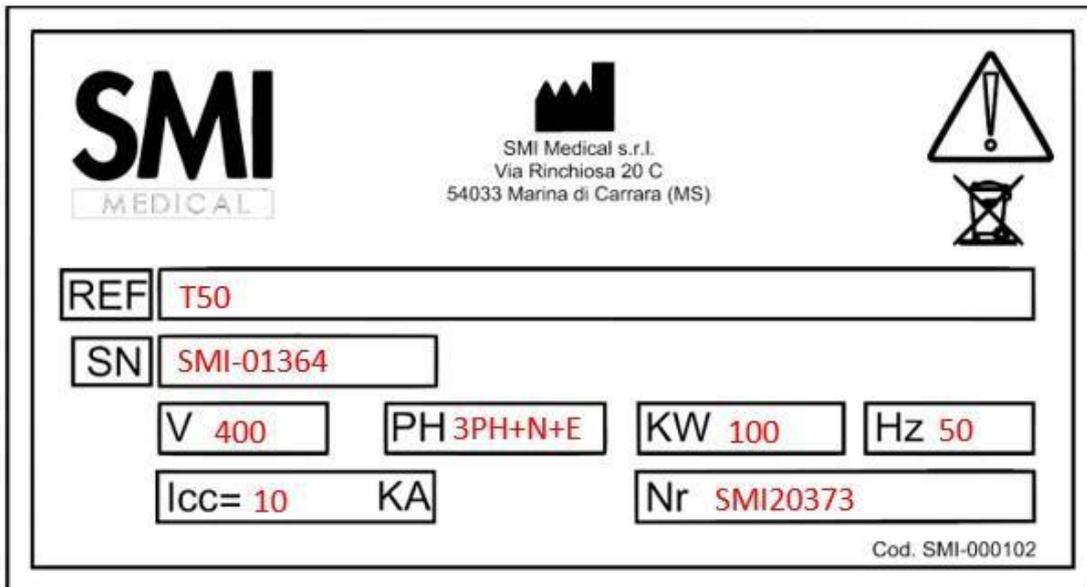
<b>Test Report History:</b> This report may consist of more than one report and is only valid with additional or previous issued reports:	
<b>Report Ref. No.</b>	<b>Item</b>
S.318.01_SAF104_B0.0	First issue
<b>Tests performed (name of test and test clause):</b> 4.4, Tests (4.4.1 to 4.4.4) + 4.4.2.102 of IEC 61010-2-040 particular standard 5, Markings (5.1.1 to 5.1.3, 5.4) 6, Protection against electric shock 10, Equipment temperature limits and resistance to heat (10.1 to 10.4) 16, Hazards resulting from application Appended Table 4.4, Testing in Single Fault Condition – Results (Form A.1) Appended Table 5.1.3 c), Mains supply (Form A.2) Appended Table 6.2, List of accessible parts (Form A.4) Appended Table 6, Values in Normal Condition (Form A.5) Appended Table 6.3.2, Values in Single Fault Condition (Form A.6) Appended Table 6.5.2.5, Bonding impedance of permanently connected equipment (Form A.10) Appended Table 6.7, Insulation requirements – Block diagram of system (Form A.14) Appended Table 6.7, Insulation requirements – Clearances and Creepages (Form A.15) Appended Table 6.8, Dielectric strength test (Form A.18) Appended Table 10, Temperature measurements (Forms A.26A)	<b>Testing location:</b> SMI Medical S.r.l. Via Piemonte, 112 - 56035 Casciana Terme Lari (PI)
<input checked="" type="checkbox"/> <b>The product fulfils the requirements of IEC 61010-1:2010 + A1:2016.</b>	

**Copy of marking plate:**

The artwork below may be only a draft.



**Main label**



**Electrical cabinet label**

**Copy of marking plate:**

The artwork below may be only a draft.

					
		SMI Medical s.r.l Via Rinchiosa 20 C 54033 Marina di Carrara (MS)			
CAMERA/Chamber			INTERCAPEDINE/Jacket		
P.S. max	<input type="text" value="+3,5"/>	bar	P.S. max	<input type="text" value="+3,5"/>	bar
P.S. min	<input type="text" value="-1"/>	bar	P.S. min	<input type="text" value="0"/>	bar
T.S. max	<input type="text" value="+148"/>	°C	T.S. max	<input type="text" value="+148"/>	°C
T.S. min	<input type="text" value="-10"/>	°C	T.S. min	<input type="text" value="-10"/>	°C
P.T.	<input type="text" value="+5,8"/>	bar	P.T.	<input type="text" value="+7,4"/>	bar
V	<input type="text" value="1290"/>	L	V	<input type="text" value="352"/>	L
STANDARD CODE	<input type="text" value="UNI EN 13445:2021"/>				
GROUP	<input type="text" value="2"/>	SN	<input type="text" value="SMI-01364"/>		
DATE OF TESTING MANUFACTURING	<input type="text" value="09-2023"/>				
Cod. SMI-000104					

**Steam chamber label**

					
		SMI Medical s.r.l Via Rinchiosa 20 C 54033 Marina di Carrara (MS)			
P.S. min	<input type="text" value="0"/>	bar	P.S. max	<input type="text" value="+4"/>	bar
T.S. min	<input type="text" value="-10"/>	°C	T.S. max	<input type="text" value="+250"/>	°C
V	<input type="text" value="115"/>	L	P.T.	<input type="text" value="+7,26"/>	bar
kg/h	<input type="text" value="139"/>				
STANDARD CODE	<input type="text" value="UNI EN 13445:2021"/>				
GROUP	<input type="text" value="2"/>	SN	<input type="text" value="SMI-01365"/>		
DATE OF TESTING MANUFACTURING	<input type="text" value="09-2023"/>				
Cod. SMI-000103					

**Steam generator label**

<b>GENERAL INFORMATION</b>	
<b>Test item particulars:</b>	
Type of item .....	Laboratory
Description of equipment function.....	Waste treatment Device
Connection to MAINS supply .....	Permanent
Overvoltage category .....	II
POLLUTION DEGREE.....	2
Means of protection.....	Class I (PE connected)
Environmental conditions .....	Normal / <del>Extended</del> (Specify):
For use in wet locations.....	Yes / <del>No</del>
Equipment mobility.....	<del>Portable</del> / <del>Hand-held</del> / <del>Floor-standing</del> / <del>Fixed</del> / Built-in
Operating conditions.....	Continuous / <del>Short-time</del> / <del>Intermittent</del>
Overall size of equipment (W x D x H).....	2400 x 1560 x 1960 mm
Mass of equipment (kg).....	3400 kg (without water)
Marked degree of protection to IEC 60529 .....	Not marked (ordinary equipment)
<b>Possible test case verdicts:</b>	
- Test case does not apply to the test object .....	N/A (Not Applicable)
- Test object does meet the requirement.....	P (Pass)
- Test object does not meet the requirement.....	F (Fail)
<b>Testing:</b>	
Date of receipt of test item.....	2024/06/18 (SN SMI-01364)
Date (s) of performance of tests .....	2024/06/18 to 2024/07/23
<b>General remarks:</b>	
<p>The test results presented in this report relate only to the object tested.  This report shall not be reproduced, except in full, without the written approval of the issuing testing laboratory.  "(see ENCLOSURE #)" refers to additional information appended to the report.  "(see Form A.xx)" refers to a Table appended to the report.  Bottom lines for measurement Tables Forms A.xx are optional if used as record.</p>	
Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
Name and address of factory (ies) .....	

**General product information and other remarks**

See Use and maintenance manual of medical waste treatment -Truster Rev. 1.0 date 2024/07/22.

**Description of model differences**

/

**Description of special features**

/

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
<b>4</b>	<b>TESTS</b>		-
4.4	Testing in SINGLE FAULT CONDITIONS		-
4.4.1	Fault tests	(see Form A.1)	P
4.4.2	Application of SINGLE FAULT CONDITIONS		P
4.4.2.1	SINGLE FAULT CONDITIONS not covered by 4.4.2.2 to 4.4.2.14		N/A
4.4.2.2	PROTECTIVE IMPEDANCE		N/A
4.4.2.3	PROTECTIVE CONDUCTOR	(see Form A.6)	P
4.4.2.102	Failure, or partial failure, of the MAINS supply		—
	Following tests have been conducted:	See below	P
	Operate at 90 % of RATED voltage for one cycle	360 V, 3N~	P
	Operate at 110 % of RATED voltage for one cycle	440 V, 3N~	P
	Set to 90 % of RATED voltage for 5 min	360 V, 3N~	P
	reduced (gradually 10 V / min) to ..... :	345 V, 3N~	P
	Reset to RATED voltage	400 V, 3N~	P
4.4.3	Duration of tests	(see Form A.1)	—
4.4.4	Conformity after application of fault conditions	(see Forms A.1 and A.6)	P

<b>5</b>	<b>MARKING AND DOCUMENTATION</b>		-
<b>5.1</b>	<b>Marking</b>		-
5.1.1	General		-
	Required equipment markings		—
	– Visible from the exterior; or	Main label: see Copy of marking plate section	P
	– Visible after removing cover or opening door	Electrical cabinet and steam generator labels: see Copy of marking plate section	P
	– Visible after removal from a rack or panel		N/A
	Not put on parts which can be removed by an operator		P
	Letter symbols (IEC 60027) used		P
	Graphic symbols of Table 1 used		P
5.1.2	Identification		-
	Equipment is identified by:		—
	a) Manufacturer's or supplier's name or trademark	Manufacturer's name (followed by complete address) and Trademark	P
	b) Model number, name or other means	REF and SN	P
	Manufacturing location identified	Manufacturing location identified	P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.1.3	MAINS supply		-
	Equipment is marked as follows:		—
	a) Nature of supply:		—
	1) a.c. RATED MAINS frequency or range of frequencies .....	50/60 Hz	—
	2) d.c. with symbol 1.....	/	—
	b) RATED supply voltage(s) or range .....	400 V, 3N~	—
	c) Max. RATED power (W or VA) or input current .....	100 kVA	—
	The marked value not less than 90 % of the maximum value	(see Form A.2)	P
	If more than one voltage range:	Single voltage value	—
	Separate values marked; or		N/A
	Values differ by less than 20 %		N/A
	d) OPERATOR-set for different RATED supply voltages:	Not provided	—
	Indicates the equipment set voltage		N/A
	PORTABLE EQUIPMENT indication is visible from the exterior	Permanently installed	N/A
	Changing the setting changes the indication		N/A
	e) Accessory MAINS socket-outlets accepting standard MAINS plugs are marked:	Not provided	—
	With the voltage if it is different from the MAINS supply voltage.....	See above	—
	For use only with specific equipment	See above	N/A
	If not marked for specific equipment it is marked with:	See above	—
	The maximum RATED current or power; or	See above	N/A
	Symbol 14 with full details in the documentation	See above	N/A
<b>5.4</b>	<b>Documentation</b>		-
5.4.1	General		-
	Equipment is accompanied by documentation for safety purposes for OPERATOR or RESPONSIBLE BODY	See Attachment No. 3	P
	Safety documentation for service personnel authorized by the manufacturer	See Attachment No. 3	P
	Documentation necessary for safe operation is provided in printed media or	Documentation provided both in printed and electronic media	P
	in electronic media if available at any time	See above	P
	Documentation includes:		—
	a) Intended use	Use and maintenance manual, Chapter Intended use	P
	b) Technical specification	See Attachment No. 3	P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Name and address of manufacturer or supplier	See below	P
	d) Information specified in 5.4.2 to 5.4.6	See below	P
	e) Information to mitigate residual RISK (see also subclause 17)	Use and maintenance manual	P
	f) Accessories for safe operation of the equipment specified	Use and maintenance manual	P
	g) Guidance provided to check correct function of the equipment, if incorrect reading may cause a HAZARD from harmful or corrosive substances of HAZARDOUS live parts	Use and maintenance manual	P
	h) Instructions for lifting and carrying	Installation manual	P
	Warning statements and a clear explanation of warning symbols:		—
	– provided in the documentation; or	Provided in the documentation	P
	– information is marked on the equipment	Marked on the equipment (see also Copy of marking plate section)	P
5.4.2	Equipment RATINGS		-
	Documentation includes:		—
	a) Supply voltage or voltage range..... :	Installation manual	—
	Frequency or frequency range .....	See above	—
	Power or current rating..... :	See above	—
	b) Description of all input and output connections in accordance with 6.6.1 a)	See above	P
	c) RATING of insulation of external circuits in accordance with 6.6.1 b)	See above	P
	d) Statement of the range of environmental conditions (refer to 1.4):		—
	1) indoor or outdoor use,	Installation manual	P
	2) altitude,	See above	P
	3) temperature,	See above	P
	4) relative humidity,	See above	P
	5) MAINS supply voltage fluctuations,	See above	P
	6) OVERVOLTAGE CATEGORY,	See above	P
	7) WET LOCATION, if applicable,		N/A
	8) POLLUTION DEGREE of the intended environment	See above	P
	e) Degree of ingress protection (IEC 60529)		N/A
	f) If impact rating less than 5 J:		—

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	IK code in accordance to IEC 62262 marked; or		N/A
	symbol 14 of Table 1 marked, with		N/A
	RATED energy level and test method stated		N/A
5.4.3	Equipment installation		-
	Documentation includes instructions for:		—
	a) Assembly, location and mounting requirements	Installation manual	P
	b) Instructions for protective earthing	Installation manual	P
	c) Connections to supply	Installation manual	P
	d) PERMANENTLY CONNECTED EQUIPMENT:		—
	1) Supply wiring requirements	Installation manual	P
	2) If external switch or circuit-breaker, requirements and location recommendation	See above	P
	e) Ventilation requirements		N/A
	f) Safety characteristics for special external services (e.g. maximum and minimum temperature, pressure, flow of air, cooling liquid)	Installation manual	P
	g) Instructions relating to sound level		N/A
5.4.4	Equipment operation		-
	Instructions for use include:		—
	a) Identification and description of operating controls	Use and maintenance manual	P
	b) Positioning for disconnection	See above	P
	c) Instructions for interconnection to accessories or other equipment	Use and maintenance manual	P
	d) Specification of intermittent operation limits		N/A
	e) Explanation of symbols used	Use and maintenance manual	P
	f) Replacement of consumable materials		N/A
	g) Cleaning and decontamination	Use and maintenance manual	P
	h) Listing of any poisonous or injurious gases and quantities	Not provided	N/A
	i) RISK reduction procedures relating to flammable liquids (see 9.5 c)	Not provided	N/A
	j) RISK reduction procedures relating burn from surfaces permitted to exceed limits of 10.1	Not provided	N/A
	Additional precautions for IEC 60950 conforming equipment in regard to moistures and liquids		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	A statement about protection impairment if used in a manner not specified by the manufacturer	Use and maintenance manual	P
5.4.5	Equipment maintenance and service		-
	Instructions for RESPONSIBLE BODY include:		—
	Instructions sufficient in detail permitting safe maintenance and inspection and continued safety:		—
	Instruction against the use of detachable MAINS supply cord with inadequate RATING	Permanently installed	N/A
	Specific battery type of user replaceable batteries	Not provided	N/A
	Any manufacturer specified parts	Use and maintenance manual	P
	RATING and characteristics of fuses	Use and maintenance manual	P
	Instructions include following subjects permitting safe servicing and continued safety:		—
	a) Product specific RISKS may affect service personnel	Use and maintenance manual	P
	b) Protective measures for these RISKS	See above	P
	c) Verification of the safe state after repair	See above	P
5.4.6	Integration into systems or effects resulting from special conditions		N/A
	Aspects described in documentation		N/A

<b>6</b>	<b>PROTECTION AGAINST ELECTRIC SHOCK</b>		-
<b>6.1</b>	<b>General</b>	(see Forms A.14 and A.15)	P
6.1.1	Requirements		-
	Protection against electric shock maintained in NORMAL CONDITION and SINGLE FAULT CONDITION		P
	ACCESSIBLE parts not HAZARDOUS LIVE	Not hazardous live	P
	Voltage, current, charge or energy below the limits in NORMAL CONDITION and in SINGLE FAULT CONDITION between:		—
	ACCESSIBLE parts and earth		P
	two ACCESSIBLE parts on same piece of the equipment within a distance of 1.8 m		P
	Conformity is checked by the determination of 6.2 and 6.3 followed by the tests of 6.4 to 6.11		P
6.1.2	Exceptions	None	-
	Following HAZARDOUS LIVE parts may be ACCESSIBLE to an OPERATOR:		—
	a) parts of lamps and lamp sockets after lamp removal		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) parts to be replaced by OPERATOR only by the use of tool and warning marking		N/A
	Those parts not HAZARDOUS LIVE 10 s after interruption of supply		N/A
	Capacitance test if charge is received from internal capacitor		N/A
<b>6.2</b>	<b>Determination of ACCESSIBLE parts</b>	(see Form A.4)	P
6.2.1	General		-
	Unless obviously determination of ACCESSIBLE parts as specified in 6.2.2 to 6.2.4		P
6.2.2	Examination		-
	– with jointed test finger (as specified B.2)		P
	– with rigid test finger (as specified B.1) and a force of 10 N		P
6.2.3	Openings above parts that are HAZARDOUS LIVE	Not provided	N/A
	– test pin with length of 100 mm and 4 mm in diameter applied		N/A
6.2.4	Openings for pre-set controls	Not provided	N/A
	– test pin with length of 100 mm and 3 mm in diameter applied		N/A
<b>6.3</b>	<b>Limit values for ACCESSIBLE parts</b>		-
6.3.1	Levels in NORMAL CONDITION	(see Form A.5)	P
	a) Voltage limits less than 30 V r.m.s. and 42,4 V peak or 60 V d.c.		P
	for WET LOCATIONS voltage limits less than 16 V r.m.s. and 22,6 V peak or 35 V d.c.		N/A
	Voltages are not HAZARDOUS LIVE the levels of:		—
	b) Current less than 0,5 mA r.m.s. for sinusoidal, 0,7 mA peak non-sinusoidal or mixed frequencies or 2 mA d.c. when measured with measuring circuit A.1 or A.2 if less than 100 Hz		P
	for WET LOCATIONS measuring circuit A.4 used		N/A
	70 mA r.m.s. when measured with circuit A.3 for higher frequencies		N/A
	c) Levels of capacitive charge or energy less:		—
	1) 45 $\mu$ C for voltages up to 15 kV peak or d.c. or line A of Figure 3		N/A
	2) 350 mJ stored energy for voltages above 15 kV peak or d.c.		N/A
6.3.2	Levels in SINGLE FAULT CONDITION	(see Form A.6)	P
	a) Voltage limits less than 50 V r.m.s. and 70 V peak or 120 V d.c.		P

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	for WET LOCATIONS voltage limits less than 33 V r.m.s. and 46,7 V peak or 70 V d.c.		N/A
	Voltages are not HAZARDOUS LIVE the levels of:		—
	b) Current less than 3,5 mA r.m.s. for sinusoidal, 5 mA peak non-sinusoidal or mixed frequencies or 15 mA d.c. when measured with measuring circuit A.1 or A.2 if less than 100 Hz		P
	for WET LOCATIONS measuring circuit A.4 used		N/A
	500 mA r.m.s. when measured with circuit A.3 for higher frequencies		N/A
	c) Levels of capacitive charge or energy less line B of Figure 3		N/A
<b>6.4</b>	<b>Primary means of protection</b>		-
6.4.1	General		-
	ACCESSIBLE parts prevented from being HAZARDOUS LIVE by one or more of following means:	(see Form A.4)	—
	a) ENCLOSURES or PROTECTIVE BARRIERS (see 6.4.2)	Enclosure	P
	b) BASIC INSULATION (see 6.4.3)	Basic insulation	P
	c) Impedance (see 6.4.4)		N/A
6.4.2	ENCLOSURES or PROTECTIVE BARRIERS	(see Forms A.15 and A.16)	P
	– meet rigidity requirements of 8.1		P
	– meet requirements for BASIC INSULATION, if protection is provided by insulation		P
	– meet requirements of 6.7 for CREEPAGE and CLEARANCES between ACCESSIBLE parts and HAZARDOUS live parts, if protection is provided by limited access		P
6.4.3	BASIC INSULATION	(see Forms A.15 and A.16)	P
	– meet CLEARANCE, CREEPAGE DISTANCE and solid insulation requirements of 6.7		P
6.4.4	Impedance		N/A
	Impedance used as primary means of protection meets all the following requirements:		—
	a) limits current or voltage to level of 6.3.2		N/A
	b) RATED for maximum WORKING VOLTAGE and the amount of power it will dissipate		N/A
	c) CLEARANCE, CREEPAGE DISTANCE between terminations of the impedance meet requirements of BASIC INSULATION of 6.7		N/A
<b>6.5</b>	<b>Additional means of protection in case of SINGLE FAULT CONDITION</b>		-
6.5.1	General		-

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ACCESSIBLE parts are prevented from becoming HAZARDOUS live by the primary means of protection and supplemented by one of:	(see Form A.4)	—
	a) PROTECTIVE BONDING (see 6.5.2)		P
	b) SUPPLEMENTARY INSULATION (see 6.5.3)		P
	c) automatic disconnection of the supply (see 6.5.5)		N/A
	d) current- or voltage-limiting device (see 6.5.6)		N/A
	Alternatively, one of the single means of protection is used:		—
	e) REINFORCED INSULATION (see 6.5.3)	Touch screen display	P
	f) PROTECTIVE IMPEDANCE (see 6.5.4)		N/A
6.5.2	PROTECTIVE BONDING	(see Form A.10)	P
6.5.2.1	General		-
	ACCESSIBLE conductive parts, may become HAZARDOUS LIVE in SINGLE FAULT CONDITION:	(see Form A.4)	—
	Bonded to the PROTECTIVE CONDUCTOR TERMINAL; or	Bonded to the protective earth terminal	P
	Separated by conductive screen or barrier bonded to PROTECTIVE CONDUCTOR TERMINAL		N/A
6.5.2.2	Integrity of PROTECTIVE BONDING		—
	a) PROTECTIVE BONDING consists of directly connected structural parts or discrete conductors or both; and withstands thermal and dynamic stresses	Directly connected structural parts and/or discrete conductors	P
	b) Soldered connections:	Not used	—
	Independently secured against loosening		N/A
	Not used for other purposes		N/A
	c) Screw connections are secured	Secured against accidental loosening	P
	d) PROTECTIVE BONDING not interrupted; or	Not interrupted	P
	except as removable part that carries MAINS SUPPLY input connection to the whole equipment		N/A
	e) Any movable PROTECTIVE BONDING connection specifically designed and meets 6.5.2.4	Not provided	N/A
	f) No external metal braid of cables used (not regarded as PROTECTIVE BONDING)	Not used	P
	g) IF MAINS SUPPLY passes through:		—
	Means provided for passing protective conductor;		N/A
	Impedance meets 6.5.2.4		N/A
	h) Protective conductors bare or insulated, if insulated, green/yellow	Green/yellow	P
	Exceptions:		—

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	1) earthing braids;	Not used	N/A
	2) internal protective conductors etc.;		N/A
	Green/yellow not used for other purposes	Not used for other purposes	P
	TERMINAL suitable for connection of a PROTECTIVE CONDUCTOR and meets 6.5.2.3		
6.5.2.3	PROTECTIVE CONDUCTOR TERMINAL		—
	a) Contact surfaces are metal		P
	b) Appliance inlet used	Not used	N/A
	c) For rewirable cords and PERMANENTLY CONNECTED EQUIPMENT, PROTECTIVE CONDUCTOR TERMINAL is close to MAINS supply TERMINALS	Closed to mains supply terminals	P
	d) If no MAINS supply is required, any PROTECTIVE CONDUCTOR TERMINAL:	See above	—
	Is near terminals of circuit for which protective earthing is necessary		N/A
	External if other terminals external		N/A
	e) Equivalent current-carrying capacity to MAINS supply TERMINALS		P
	f) If plug-in, makes first and breaks last		N/A
	g) If also used for other bonding purposes, PROTECTIVE CONDUCTOR:	Not used for other bonding purposes	—
	Applied first;		N/A
	Secured independently;		N/A
	Unlikely to be removed by servicing		N/A
	h) PROTECTIVE CONDUCTOR of measuring circuit:		—
	1) Current RATING equivalent to measuring circuit TERMINAL;		N/A
	2) PROTECTIVE BONDING: not interrupted by any switch or interrupting device		N/A
	i) FUNCTIONAL EARTH TERMINALS allow independent connection	Not provided	N/A
	j) If a binding screw used for PROTECTIVE CONDUCTOR TERMINAL:		—
	Suitable size for bond wire		N/A
	Not smaller than M 4		N/A
	At least 3 turns of screw engaged		N/A
	Passes tightening torque test		N/A
	k) Contact pressure not capable being reduced by deformation of materials		N/A
6.5.2.4	Impedance of PROTECTIVE BONDING of plug-connected equipment	Permanently installed equipment – See below	N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Impedance between PROTECTIVE CONDUCTOR TERMINAL and each ACCESSIBLE part where PROTECTIVE BONDING is specified, is:		—
	– less than 0,1 Ohm; or		N/A
	– less than 0,2 Ohm if equipment is provided with non-detachable cord		N/A
6.5.2.5	Impedance of PROTECTIVE BONDING of PERMANENTLY CONNECTED EQUIPMENT	(see Form A.10)	P
6.5.2.6	Transformer PROTECTIVE BONDING screen	Not provided	N/A
	Transformer provided with screen for PROTECTIVE BONDING:		—
	screen bonding consists of directly connected structural parts or discrete conductors or both; and withstands thermal and dynamic stresses (see 6.5.2.2 a )		N/A
	screen bonding with soldered connection (see 6.5.2.2 b ) is:		—
	– Independently secured against loosening		N/A
	– Not used for other purposes		N/A
6.5.3	SUPPLEMENTARY and REINFORCED INSULATION		-
	Meet CLEARANCE, CREEPAGE DISTANCE and solid insulation requirements of 6.7	See sub-clause 6.7	P
6.5.4	PROTECTIVE IMPEDANCE	Not used	-
	Limits current or voltage to level of 6.3.1 in NORMAL and to level of 6.3.2 in SINGLE FAULT CONDITION		N/A
	CLEARANCE, CREEPAGE DISTANCE between terminations of the impedance meet requirements of DOUBLE or REINFORCED INSULATION of 6.7		N/A
	The PROTECTIVE IMPEDANCE consists of one or more of the following:		—
	a) appropriate single component suitable for safety and reliability for protection, it is:		—
	1) RATED twice the maximum WORKING VOLTAGE		N/A
	2) resistor RATED for twice the power dissipation for maximum WORKING VOLTAGE		N/A
	b) combination of components		N/A
	Single electronic device not used as PROTECTIVE IMPEDANCE		N/A
6.5.5	Automatic disconnection of the supply	Not provided	-
	a) RATED to disconnect the load within time specified in Figure 2		N/A
	b) RATED for the maximum load conditions of the equipment		N/A
6.5.6	Current- or voltage-limiting devices	Not provided	N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Device complies with all of:		—
	a) RATED to limit the current or voltage to the level of 6.3.2		N/A
	b) RATED for the maximum WORKING VOLTAGE; and		N/A
	RATED for the maximum operational current if applicable		N/A
	c) CLEARANCE, CREEPAGE DISTANCE between terminations of the impedance meet requirements of SUPPLEMENTARY INSULATION of 6.7		N/A
<b>6.6</b>	<b>Connections to external circuits</b>		-
6.6.1	General		-
	Connections do not cause ACCESSIBLE parts of the following to become HAZARDOUS LIVE in NORMAL CONDITION or SINGLE FAULT CONDITION:		—
	– the external circuits	See Appended Tables 6.7 (ELV circuits to ethernet connection)	P
	– the equipment	See Appended Tables 6.7	P
	Protection achieved by separation of circuits; or	See Appended Tables 6.7	P
	short circuit of separation does not cause a HAZARD	See above	N/A
	Instructions or markings for each terminal include:		—
	a) RATED conditions for TERMINAL		N/A
	b) Required RATING of external circuit insulation		N/A
6.6.2	TERMINALS for external circuits		-
	TERMINALS which receive a charge from an internal capacitor are not HAZARDOUS LIVE after 10 s of interrupting supply connection		N/A
6.6.3	Circuits with terminals which are HAZARDOUS LIVE	Not provided	N/A
	These circuits are:		—
	Not connected to ACCESSIBLE conductive parts; or		N/A
	Connected to ACCESSIBLE conductive parts, but are not MAINS CIRCUITS and have one TERMINAL contact at earth potential		N/A
	No ACCESSIBLE conductive parts are HAZARDOUS LIVE		N/A
6.6.4	Terminals for stranded conductors		-
	No RISK of accidental contact because:		—
	– Located or shielded		P
	– Self-evident or marked whether or not connected to ACCESSIBLE conductive parts		N/A
	Complies as applicable:		—
	a) Manufacturer's specified maximum length of removed insulation, or		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) 8 mm length of insulation removed		P
<b>6.7</b>	<b>Insulation requirements</b>	(see Form A.14)	P
6.7.1	The nature of insulation		-
6.7.1.1	General		-
	Insulation between ACCESSIBLE parts or between separate circuits consist of CLEARANCES, CREEPAGE DISTANCES and solid insulation if provided as protection against a HAZARD		P
6.7.1.2	CLEARANCES		-
	Required CLEARANCES reflecting factors of 6.7.1.1	(see Forms A.14 and A.15)	P
	Equipment rated for operating altitude greater than 2000 m correction factor of Table 3 of 61010-1 applied	≤ 2000 m	N/A
6.7.1.3	CREEPAGE DISTANCES		-
	Required CREEPAGE DISTANCES reflecting factors of 6.7.1.1 a) to d)	(see Forms A.14 and A.15)	P
	CTI material group reflected by requirements		P
	CTI test performed		N/A
6.7.1.4	Solid insulation		-
	Required solid insulation reflecting factors of 6.7.1.1 a) to d)	(see Forms A.14 and A.15)	P
6.7.1.5	Requirements for insulation according to type of circuit	(see Forms A.14 and A.15)	P
	a) 6.7.2 MAINS circuits of OVERVOLTAGE CATEGORY II up to nominal supply voltage of 300 V	230 V Lines to Neutral or Earth	P
	b) 6.7.3 secondary circuits separated from circuits defined in a) by transformer		N/A
	c) K.1 MAINS circuits of OVERVOLTAGE CATEGORY III and IV or OVERVOLTAGE CATEGORY II over 300 V		N/A
	d) K.2 secondary circuits separated from circuits defined in c) by transformer		N/A
	e) K.3 circuits having one or more of:		—
	1) maximum TRANSIENT OVERVOLTAGE is limited to known level below the level of MAINS CIRCUIT		P
	2) maximum TRANSIENT OVERVOLTAGE above the level of MAINS CIRCUIT		N/A
	3) WORKING VOLTAGE is the sum of more than one circuit or a mixed voltage		N/A
	4) WORKING VOLTAGE includes recurring peak voltage, may include non-sinusoidal or non-periodic waveform		N/A
	5) WORKING VOLTAGE with a frequency above 30 kHz		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.7.2	Insulation for MAINS CIRCUITS of OVERVOLTAGE CATEGORY II with a nominal supply voltage up to 300 V	230 V Lines to Neutral or Earth	-
6.7.2.1	CLEARANCES and CREEPAGE DISTANCES	(see Forms A.14 and A.15)	—
	Values for MAINS CIRCUITS of Table 4 are met		P
	Coatings to achieve reduction to POLLUTION DEGREE 1 comply with requirements of Annex H	Not provided	N/A
6.7.2.2	Solid insulation		-
6.7.2.2.1	General		-
	Withstands electrical and mechanical stresses in normal use and all RATED environmental conditions of 1.4		P
	Equipment passed voltage tests of 6.8.3 with values of Table 5	(see Form A.18)	P
	Complies as applicable:		—
	a) ENCLOSURE or PROTECTIVE BARRIER of Clause 8		P
	b) moulded and potted parts requirements of 6.7.2.2.2		N/A
	c) inner layers of printed wiring boards requirements of 6.7.2.2.3		N/A
	d) thin-film insulation requirements of 6.7.2.2.4		N/A
6.7.2.2.2	Moulded and potted parts		—
	Conductors between same two layers are separated by at least 0,4 mm after moulding is completed		N/A
6.7.2.2.3	Inner insulating layers of printed wiring boards		—
	Separated by at least 0,4 mm between same two layers		N/A
	REINFORCED INSULATION have adequate electric strength; one of following methods used:		—
	a) thickness of insulation is at least 0,4 mm		N/A
	b) insulation is assembled of minimum two separate layers, each RATED for test voltage of Table 5 for BASIC INSULATION		N/A
	c) insulation is assembled of minimum two separate layers, where the combination is rated for test voltage of Table 5 for REINFORCED INSULATION		N/A
6.7.2.2.4	Thin-film insulation		—
	Conductors between same two layers are separated by applicable CLEARANCES and CREEPAGE DISTANCE of 6.7.2.1		N/A
	REINFORCED INSULATION has adequate electric strength; one of the following methods used:		—
	a) thickness through the insulation at least 0,4 mm		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) insulation is assembled of min. two separate layers, each RATED for test voltage of Table 5 for BASIC INSULATION		N/A
	c) insulation is assembled of min. three separate layers, where the combination of two layers passed voltage tests of 6.8.3 with values of Table 5 for REINFORCED INSULATION		N/A
6.7.3	Insulation for secondary circuits derived from MAINS CIRCUITS of OVERVOLTAGE CATEGORY II up to 300 V		-
6.7.3.1	General		-
	Secondary circuits where separation from MAINS CIRCUITS is achieved by a transformer providing:		—
	– REINFORCED INSULATION	Internal SMPS units comply with their relevant IEC standard requirements	P
	– DOUBLE INSULATION		N/A
	– screen connected to the PROTECTIVE CONDUCTOR TERMINAL		N/A
6.7.3.2	CLEARANCES	(see Forms A.14 and A.15)	P
	a) meet the values of Table 6 for BASIC INSULATION and SUPPLEMENTARY INSULATION; or	Internal SMPS units comply with their relevant IEC standard requirements	P
	twice the values of Table 6 for REINFORCED INSULATION; or		N/A
	b) pass the voltage tests of 6.8 with values of Table 6;		N/A
	with following adjustments:		—
	1) values for reinforced insulation are 1,6 times the values for basic insulation		N/A
	2) if operating altitude is greater than 2000 m values of CLEARANCES multiplied with factor of Table 3		N/A
	3) minimum CLEARANCE is 0,2 mm for POLLUTION DEGREE 2 and 0,8 mm for POLLUTION DEGREE 3		N/A
6.7.3.3	CREEPAGE DISTANCES	(see Forms A.14 and A.15)	P
	Based on WORKING VOLTAGE meets the values of Table 7 for BASIC and SUPPLEMENTARY INSULATION		P
	Values for REINFORCED INSULATION are twice the values of BASIC INSULATION		N/A
	Coatings to achieve reduction to POLLUTION DEGREE 1 comply with requirements of Annex H		N/A
6.7.3.4	Solid insulation		-
6.7.3.4.1	General		-
	Withstands electrical and mechanical stresses in normal use and all RATED environmental conditions of 1.4		—

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Equipment passed voltage test of 6.8.3.1 for 5 s with VALUES of Table 6 for BASIC and SUPPLEMENTARY INSULATION	(see Form A.18)	P
	values for REINFORCED INSULATION are 1,6 times the values of BASIC INSULATION		N/A
	b) if WORKING VOLTAGE exceeds 300 V, equipment passed voltage test of 6.8.3.1 for 1 min with a test voltage of 1,5 times working voltage for BASIC or SUPPLEMENTARY INSULATION		N/A
	value for REINFORCED INSULATION are twice the WORKING VOLTAGE		N/A
	Complies as applicable:		—
	1) ENCLOSURE or PROTECTIVE BARRIER of Clause 8		N/A
	2) moulded and potted parts requirements of 6.7.3.4.2		N/A
	3) inner layers of printed wiring boards requirements of 6.7.3.4.3		N/A
	4) thin-film insulation requirements of 6.7.3.4.4		N/A
6.7.3.4.2	Moulded and potted parts		—
	Conductors between same two layers are separated by applicable distances of Table 8		N/A
6.7.3.4.3	Inner insulation layers of printed wiring boards		—
	Separated by at least the applicable distances of Table 8 between same two layers		N/A
	REINFORCED INSULATION has adequate electric strength; one of following methods used:		—
	a) thickness at least applicable distance of Table 8		N/A
	b) insulation is assembled of minimum two separate layers, each RATED for test voltage of Table 6 for BASIC INSULATION		N/A
	c) insulation is assembled of min. two separate layers, where the combination is RATED for 1,6 times the test voltage of Table 6		N/A
6.7.3.4.4	Thin-film insulation		—
	Conductors between same two layers are separated by applicable CLEARANCES and CREEPAGE DISTANCE of 6.7.3.2 and 6.7.3.3		N/A
	REINFORCED INSULATION has adequate electric strength; one of following methods used:		—
	a) thickness at least applicable distance of Table 8		N/A
	b) insulation is assembled of min. two separate layers, each RATED for test voltage of Table 6 for BASIC INSULATION		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) insulation is assembled of min. three separate layers, where the combination of two layers passed voltage tests with 1,6 times values of Table 6:		—
	a.c. test of 6.8.3.1; or		N/A
	d.c. test of 6.8.3.2 for circuits stressed only by d.c. voltages		N/A
<b>6.8</b>	<b>Procedure for voltage tests</b>	(see Forms A.14 and A.18)	P
<b>6.9</b>	<b>Constructional requirements for protection against electric shock</b>		-
6.9.1	General		-
	If a failure could cause a HAZARD:		—
	a) security of wiring connections		P
	b) screws securing removable covers		P
	c) accidental loosening		P
	d) CLEARANCES and CREEPAGE DISTANCES not reduced below the values of basic insulation by loosening of parts or wires		P
6.9.2	Insulating materials		-
	Material not to be used for safety relevant insulation:		—
	a) easily damaged materials not used	Not used	P
	b) non-impregnated hygroscopic materials not used	Not used	P
6.9.3	Colour coding		-
	Green-and-yellow insulation shall not be used except:		—
	a) protective earth conductors;		P
	b) PROTECTIVE BONDING conductors;		P
	c) potential equalization conductors;	Not provided	N/A
	d) functional earth conductors	Not provided	N/A
<b>6.10</b>	<b>Connection to MAINS supply source and connections between parts of equipment</b>		-
6.10.1	MAINS supply cords	Not provided (see Installation manual for further details about mains supply cables characteristics)	-
	RATED for maximum equipment current (see 5.1.3 c)	Mains and interconnection cords: PVC type FROR 450/750 V O.R., FROR25 O.R., FS17 and T15 used	P
	Cable complies with IEC 60227 or IEC 60245		P
	Heat-resistant if likely to contact hot parts	OLFLEX HEAT 180 SiHF type used	P
	Temperature RATING (cord and inlet).....:	PVC type: up to +70 °C Silicone type: up to +180 °C	—

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Green/yellow used only for connection to PROTECTIVE CONDUCTOR TERMINALS		P
	Detachable cords with IEC 60320 MAINS connectors:	Not provided	—
	Conform to IEC 60799; or		N/A
	Have the current RATING of the MAINS connector		N/A
6.10.2	Fitting of non-detachable MAINS supply cords		-
6.10.2.1	Cord entry	Mains supply cord entry to the electrical cabinet	—
	a) inlet or bushing with a smoothly rounded opening; or		P
	b) insulated cord guard protruding >5 D (diameter)		N/A
6.10.2.2	Cord anchorage	Permanently installed equipment	—
	Protective earth conductor is the last to take the strain		N/A
	a) cord is not clamped by direct pressure from a screw		N/A
	b) knots are not used		N/A
	c) cannot push the cord into the equipment to cause a HAZARD		N/A
	d) no failure of cord insulation in anchorage with metal parts		N/A
	e) not to be loosened without a tool		N/A
	f) cord replacement does not cause a HAZARD and method of strain relief is clear		N/A
	Push-pull and or torque test		N/A
6.10.3	Plugs and connectors	Permanently installed equipment	-
	MAINS supply plugs, connectors etc., conform with relevant specifications		N/A
	If equipment supplied at voltages below 6.3.2.a) or from a sole source:		—
	Plugs of supply cords do not fit MAINS sockets above rated SUPPLY voltage		N/A
	MAINS type plugs used only for connection to MAINS supply		N/A
	Plug pins which receive a charge from an internal capacitor		N/A
	Accessory MAINS socket outlets:	Not provided	—
	a) marking if accepts a standard MAINS supply plug (see 5.1.3e)		N/A
	b) input has a protective earth conductor if outlet has EARTH TERMINAL CONTACT		N/A
<b>6.11</b>	<b>Disconnection from supply source</b>		-

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.11.1	Disconnects all current-carrying conductors	See below	P
6.11.2	Exceptions	Not the case	-
6.11.3	Requirements according to type of equipment		-
6.11.3.1	PERMANENTLY CONNECTED EQUIPMENT and multi-phase equipment		-
	Employs switch or circuit-breaker	Provided with a circuit breaker	P
	If switch or circuit-breaker is not part of the equipment, documentation requires:	See above	—
	a) switch or circuit-breaker to be included in building installation		N/A
	b) suitable location easily reached		N/A
	c) marking as disconnecting for the equipment		N/A
6.11.3.2	Single-phase cord-connected equipment		N/A
	Equipment is provided with one of the following:		—
	a) switch or circuit-breaker		N/A
	b) appliance coupler (disconnectable without tool)		N/A
	c) separable plug (without locking device)		N/A
6.11.4	Disconnecting devices		-
6.11.4.1	General		-
	Disconnecting device part of equipment		P
	Electrically close to the SUPPLY		P
	Power-consuming components not electrically located between the supply source and the disconnecting device		P
	Except electromagnetic interference suppression circuits permitted to be located on the supply side of the disconnecting device	Not the case	N/A
6.11.4.2	Switches and circuit-breakers		-
	When used as disconnection device:		—
	Circuit breaker meets the relevant requirements IEC 60947-2 and is suitable for the application		P
	Switch meets the relevant requirements IEC 60947-3 and is suitable for the application		N/A
	Marked to indicate function .....		—
	Not incorporated in MAINS cord	Not incorporated	P
	Does not interrupt PROTECTIVE EARTH CONDUCTOR		P
6.11.4.3	Appliance couplers and plugs	Permanently installed equipment	N/A
	Where an appliance coupler or separable plug is used as the disconnecting device (see 6.11.3.2):		—
	Readily identifiable and easily reached by the operator		N/A

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Single-phase portable equipment cord length not more than 3 m		N/A
	PROTECTIVE EARTH CONDUCTOR connected first and disconnected last		N/A

<b>10</b>	<b>EQUIPMENT TEMPERATURE LIMITS AND RESISTANCE TO HEAT</b>		-
<b>10.1</b>	<b>Surface temperature limits for protection against burns</b>		-
	Easily touched surfaces within the limits in NORMAL and in SINGLE FAULT CONDITION:	(see Form A.26A)	—
	– at a specified ambient temperature of 40 °C		P
	– for equipment rated above 40 °C ambient temperature limits not exceeded raised by the difference to 40 °C		N/A
	Heated surfaces necessary for functional reasons exceeding specified values:	Sliding doors	—
	– Are recognizable as such by appearance or function; or		P
	– Are marked with symbol 13		N/A
	– Guards are not removable without tool		N/A
<b>10.2</b>	<b>Temperatures of windings</b>	(see Form A.26A)	-
	Limits not exceeded in:		—
	NORMAL CONDITION		N/A
	SINGLE FAULT CONDITION		N/A
<b>10.3</b>	<b>Other temperature measurements</b>		-
	Following measurements conducted if applicable:	(see Form A.26A)	—
	a) Value of 60 °C of field-wiring terminal box not exceeded	Not exceeded	P
	b) Surface of flammable liquids and parts in contact with these liquids	Not provided	N/A
	c) Surface of non-metallic ENCLOSURES		P
	d) Parts made of insulating material supporting parts connected to MAINS supply		P
	e) Terminals carrying a current more than 0,5 A		P
<b>10.4</b>	<b>Conduct of temperature tests</b>		-
10.4.1	General		-
	Tests conducted under reference test conditions and manufacturer's instructions	(see Form A.26A)	P
	Tests alternatively conducted at the least favourable ambient temperature within the RATED ambient temperature ..... :	/	—

IEC 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
10.4.2	Temperature measurement of heating equipment		-
	Tests conducted in test corner	See below	N/A
10.4.3	Equipment intended for installation in a cabinet or wall		-
	Equipment built in as specified in installation instructions	(see Form A.26A)	P

<b>16</b>	<b>HAZARDS RESULTING FROM APPLICATION</b>		-
<b>16.1</b>	<b>REASONABLY FORESEEABLE MISUSE</b>		-
	No HAZARDS arising from settings not intended and not described in the instructions	See Attachments No. 4 and No. 5	P
	Other cases of REASONABLY FORESEEABLE MISUSE addressed by RISK assessment	See Attachment No. 4	P
<b>16.2</b>	<b>Ergonomic aspects</b>		-
	Factors giving rise to a HAZARD the RISK assessment is reflecting those aspects:	See Attachment No. 4	—
	a) limitation of body dimensions		N/A
	b) displays and indicators		P
	c) accessibility and conventions of controls		P
	d) arrangement of TERMINALS		P

IEC 61010-1					
Clause	Requirement — Test			Result — Remark	Verdict
<b>4.4</b>	<b>TABLE: Testing in SINGLE FAULT CONDITION – Results</b>			<b>Form A.1</b>	
Test subclause	Fault No.	Fault description	Td 4.4.3 (NOTE)	How was test terminated Comments	Meets 4.4.4
6.3.2	1	Protective earth interrupted	00.30.00	No hazards result	P
6.3.2	2	Mains lines alternatively interrupted	00.30.00	No hazards result	P
NOTE Td = Test duration in hh:mm:ss Record dielectric strength test on Form A.18 and temperature tests on Forms A.26A and / or A.26B. Record in the comments column for each test whether carried out during or after SINGLE FAULT CONDITION.					
Supplementary information: /					

TESTED BY: A. CapoferriDATE: 2024/06/18TEST EQUIPMENT LIST ITEM: /

IEC 61010-1							
Clause	Requirement — Test			Result — Remark		Verdict	
<b>5.1.3c)</b>	<b>TABLE: MAINS supply</b>					<b>Form A.2</b>	<b>P</b>
	Marked rating .....	:	400	V		—	
	Phase .....	:	3N~			—	
	Frequency .....	:	50/60	Hz		—	
	Current .....	:	/	A		—	
	Power .....	:	/	W		—	
	Power .....	:	100	kVA		—	
Test No.	Voltage [V]	Frequency [Hz]	Current [A]	Power		Comments	
				[W]	[VA]		
1	400	50	0.6 max.	/	/	Ready to operate (stand-by condition)	
2	400	50	67.3 max.	/	/	Ready to operate (stand-by condition with steam generator energized)	
3	400	50	86.4 max.	/	101047 max.	In operation (during the treatment)	
4	400	60	0.6 max.	/	/	Ready to operate (stand-by condition)	
5	400	60	67.4 max.	/	/	Ready to operate (stand-by condition with steam generator energized)	
6	400	60	88.0 max.	/	101997 max.	In operation (during the treatment)	
NOTE – Measurements are only required for marked ratings. Initial inrush currents are not regarded.							
Supplementary information:							
Related outputs (voltage and frequency) were periodically checked through the Fluke 289 true rms multimeter s/n 36660117, property of MEQUIPE, Id. SAF.008, calibration exp. date 04.10.25.							
Power (VA) calculation formulae is $\sqrt{3}$ x voltage x current.							

TESTED BY: A. Capoferri      DATE: 2024/06/18      TEST EQUIPMENT LIST ITEM: SAF.009

IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict
<b>6.2</b>	<b>TABLE: List of ACCESSIBLE parts</b>	<b>Form A.4</b>	<b>P</b>
6.1.2	Exceptions		—
6.2	Determination of ACCESSIBLE parts		—
Item	Description	Determination method (NOTE 5)	Exception under 6.1.2 (NOTE 4)
1	Enclosure (protective earthed accessible metal parts)	V, R, J	/
2	Touch screen display enclosure	V, R, J	/
3	Thermal printer (internal parts after paper roll removal)	V, R, J	No exceptions
NOTE 1 – Test fingers and pins are to be applied without force unless a force is specified (see 6.2.2) NOTE 2 – Special consideration should be given to inadequate insulation and high voltage parts (see 6.2) NOTE 3 – Parts are considered to be ACCESSIBLE if they could be touched in the absence of any covering which is not considered to provide suitable insulation (see 6.4). NOTE 4 – Capacitance test may be required (see Form A.5). NOTE 5 – The determination methods are: V = visual; R = rigid test finger; J = jointed test finger; P3 = pin 3 mm diameter; P4 = pin 4 mm diameter.			
<b>Supplementary information:</b> Determination of accessible parts has been carried out considering instructions provided by the manufacturer through the installation layout document.			

TESTED BY: A. Capoferri      DATE: 2024/06/18      TEST EQUIPMENT LIST ITEM: IP.003, SAF.032

IEC 61010-1													
Clause	Requirement — Test							Result — Remark					Verdict
<b>6</b>	<b>TABLE: Values in NORMAL CONDITION</b>											<b>Form A.5</b>	<b>P</b>
6.1.2	Exceptions							11.2 Cleaning and decontamination					—
6.3.1	Values in NORMAL CONDITION (see NOTE 1)							11.3 Spillage					—
6.6.2	Terminals for external circuit							11.4 Overflow					—
6.10.3	Plugs and connections												—
Item (see Form A.4)	Voltage			Current				Capacitance		10 s / 5 s test (NOTE)			Comments/Conditions
	V r.m.s.	V peak	V d.c.	Test circuit A1/A2/A3	mA r.m.s.	mA peak	mA d.c.	µC	mJ	V	µC	mJ	
1, 2	< 1	/	/	A.2	< 0.01	/	/	/	/	/	/	/	Ready to operate (stand-by condition) On protective earth metal parts or touch screen display covered by a metal foil
1, 2	< 1	/	/	A.2	0.024	/	/	/	/	/	/	/	In operation (during tretment) On protective earth metal parts or touch screen display covered by a metal foil
1, 2	< 1	/	/	A.2	< 0.01	/	/	/	/	/	/	/	Ready to operate (stand-by condition) Between different parts of the enclosure (touch screen display covered by a metal foil to protective earthed accessible metal enclosure)
NOTE – A 10 s test is specified in 6.1.2 a) b). A. 5 s test is specified in 6.10.3. The capacitance level versus voltage below the limits given from figure 3 of IEC 61010-1.													
Supplementary information: Equipment supplied @ 440 V 3N, 60 Hz													

TESTED BY: A. CapoferriDATE: 2024/06/05TEST EQUIPMENT LIST ITEM: SAF.008, ATT.LAB.031

IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict

6.3.2	TABLE: Values in SINGLE FAULT CONDITION											Form A.6	P
Item  (see Form A.4)	Subclause and fault No. (see Form A.1)	Voltage			Transient (see NOTE)		Current			Capacitance	Comments		
		V r.m.s.	V peak	V d.c.	V	s	Test circuit A1/A2/A3	mA r.m.s.	mA peak	mA d.c.		μF (see NOTE)	
1, 2	1	33.80	/	/	/	/	A.2	< 1	/	/	/	Ready to operate (stand-by condition) On protective earth metal parts or touch screen display covered by a metal foil	
1, 2	1	33.80	/	/	/	/	A.2	< 1	/	/	/	In operation (during the treatment) On protective earth metal parts or touch screen display covered by a metal foil	
1, 2	1	33.80	/	/	/	/	A.2	< 1	/	/	/	Ready to operate (stand-by condition) Between different parts of the enclosure (touch screen display covered by a metal foil to protective earthed accessible metal enclosure)	
1, 2	2 Line 1 interrupted	33.80	/	/	/	/	A.2	< 1	/	/	/	Ready to operate (stand-by condition) On protective earth metal parts or touch screen display covered by a metal foil	

IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict

6.3.2	TABLE: Values in SINGLE FAULT CONDITION											Form A.6	P
Item (see Form A.4)	Subclause and fault No. (see Form A.1)	Voltage			Transient (see NOTE)		Current			Capacitance	Comments		
		V r.m.s.	V peak	V d.c.	V	s	Test circuit A1/A2/A3	mA r.m.s.	mA peak	mA d.c.		μF (see NOTE)	
1, 2	2 Line 2 interrupted	33.80	/	/	/	/	A.2	< 1	/	/	/	Ready to operate (stand-by condition) On protective earth metal parts or touch screen display covered by a metal foil	
1, 2	2 Line 3 interrupted	33.80	/	/	/	/	A.2	< 1	/	/	/	Ready to operate (stand-by condition) On protective earth metal parts or touch screen display covered by a metal foil	

NOTE – Transient voltages must be below the limits given from Figure 2 and the capacitance below the limits from figure 3 of IEC 61010-1.

Supplementary information:

Equipment supplied @ 440 V 3N, 60 Hz

TESTED BY: A. Capoferri

DATE: 2024/06/19-18

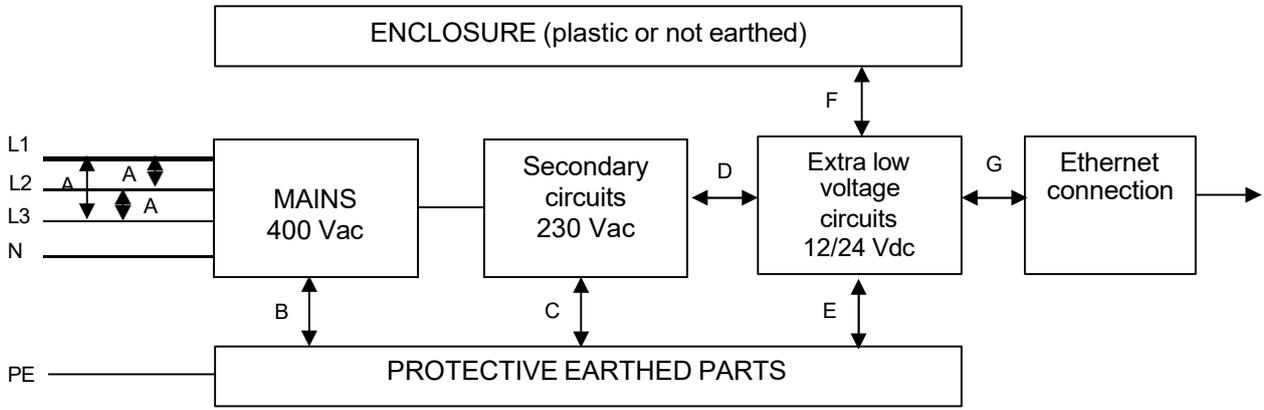
TEST EQUIPMENT LIST ITEM: SAF.008, ATT.LAB.031

IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict
<b>6.5.2.5</b>	<b>TABLE: BONDING impedance of PERMANENTLY CONNECTED EQUIPMENT Form A.10</b>		<b>P</b>
ACCESSIBLE part under test	Test current [A]	Voltage attained after 1 min (maximum 10 V) [V] / Measured resistance ( $\Omega$ )	Verdict
Openable metal panels (worst value observed)	24.2	0.47 V / 0.019 $\Omega$	Pass
Touch panel metal enclosure	24.2	0.42 V / 0.017 $\Omega$	Pass
Electrical cabinet metal enclosure	24.4	0.23 V / 0.009 $\Omega$	Pass
Chassis	24.4	0.25 V / 0.021 $\Omega$	Pass
Steam chamber door surface	24.4	0.59 V / 0.024 $\Omega$	Pass
Steam generator enclosure	24.4	0.28 V / 0.011 $\Omega$	Pass
Steam generator pump enclosure	24.4	0.40 V / 0.016 $\Omega$	Pass
Vacuum pump enclosure	25.4	0.47 V / 0.018 $\Omega$	Pass
Supplementary information:			
Measurements have been carried out between main protective earth terminal located inside the top of the device and the above listed accessible parts.			
Note: the impedance between main protective earth terminal and each accessible parts shall not exceed 0.1 $\Omega$ .			
Test current has been continuously checked through the HVAC clamp true rms meter SAF.009.			

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IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict

**6.7** **TABLE: Insulation requirements - Block diagram of system - Form A.14**



Pollution degree.....: 2

Overvoltage category .....: II

Area	Location	Insulation type (NOTE 1)	WORKING VOLTAGE			CLEARANCE (NOTE 3) [mm]	CREEPAGE DISTANCE (NOTE 3)				Test voltage (NOTE 2) [V]	Comments (NOTE 3)
			RMS [V]	Peak [V]	Freq. [Hz]		PWB [mm]	CTI	Other [mm]	CTI		
A	Between parts of opposite polarity until mains protections	BOP	400	565	50/60	3.0	---	---	6.0	---	1040 rms	
B	Between Mains and protective earthed parts	BI	230	325	50/60	1.5	---	---	3.0	---	1500 rms	
C	Between secondary circuits and protective earthed parts	BI	230	325	50/60	0.94	1.0	IIIb	2.5	---	1500 rms	
D	Between secondary and extra low voltage circuits	BI	230	325	50/60	1.5	1.5	IIIb	3.0	---	1040 rms	SMPS units (see Attachments No. 7 and 8)
E	Between extra low voltage circuits and protective earthed parts	SI	---	24dc max.	---	1.04	0.08	IIIb	1.0	---	850 rms	
F	Between extra low voltage circuits and the enclosure	BI	---	24dc max.	---	0.52	0.04	---	0.5	---	850 rms	
G	Between extra low voltage circuits and the ethernet connection	RI	230	325	50/60	3.0	3.0	IIIb	6.0	---	3000 rms	Network isolator (see Attachment No. 6)

NOTE 1 – Type of insulation:  
BI = BASIC INSULATION

NOTE 2 - Types of voltage  
Peak impulse test voltage (pulse)

NOTE 3 - OVERVOLTAGE CATEGORIES  
or POLLUTION DEGREES which differ

IEC 61010-1			
Clause	Requirement — Test	Result — Remark	Verdict
<b>6.7</b>	<b>TABLE: Insulation requirements - Block diagram of system -</b>		<b>Form A.14</b>
DI = DOUBLE INSULATION	r.m.s.	should be shown under "Comments"	
PI = PROTECTIVE IMPEDANCE	d.c.		
RI = Reinforced INSULATION	peak		
SI = Supplementary INSULATION			
BOP = BASIC insulation between parts of Opposite Polarity see also Form A.15 for further details			
Supplementary Information:			

TESTED BY: A. Capoferri      DATE: 2024/06/18      TEST EQUIPMENT LIST ITEM: /

IEC 61010-1												
Clause	Requirement — Test					Result — Remark					Verdict	
<b>6.7</b>	<b>TABLE: Insulation requirements - CLEARANCES and CREEPAGES</b>					<b>Form A.15</b>					<b>P</b>	
6.2.2	Examination					6.5.4	Protective impedance					—
6.4.2	ENCLOSURES and protective barriers					6.5.6	Current- or voltage-limiting device					—
6.4.4	Impedance					9.6.1	BASIC INSULATION between opposite polarity					—
Area	Location (See Form A.14)	Insulation type (NOTE 1)	WORKING VOLTAGE (NOTE 2)			CLEARANCE		CREEPAGE DISTANCE		CTI	Verdict	Comments
			RMS [V]	Peak [V]	Frequency [Hz]	Required [mm]	Measured [mm]	Required [mm]	Measured [mm]			
A	Between parts of opposite polarity until mains protections	BOP	400	565	50/60	3.0	8.0	6.0	8.0	IIIa/b	Pass	
B	Between Mains and protective earthed parts	BI	230	325	50/60	1.5	3.0	3.0	6.0	IIIa/b	Pass	
C	Between secondary circuits and protective earthed parts	BI	230	325	50/60	0.94	3.0	2.5	6.0	IIIa/b	Pass	
D	Between secondary and extra low voltage circuits	BI	230	325	50/60	1.5	5.0	3.0	5.0	IIIa/b	Pass	
E	Between extra low voltage circuits and protective earthed parts	SI	---	24dc max.	---	1.04	12.0	1.0	12.0	IIIa/b	Pass	
F	Between extra low voltage circuits and the enclosure	BI	---	24dc max.	---	0.52	4.0	0.5	4.0	IIIa/b	Pass	
G	Between extra low voltage circuits and the ethernet connection	RI	230	325	50/60	3.0	5.0	6.0	8.0	IIIa/b	Pass	
NOTE 1 – refer to Form A.14 for type of insulation shown in the insulation diagram						NOTE 2 - to be used for definition of required insulation (see Form A.14)						
Input supply voltage.....:		400, 3N	V	50/60	Hz							
Supplementary information: /												

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DATE: 2024/06/18

TEST EQUIPMENT LIST ITEM: \_\_\_\_\_

IEC 61010-1							
Clause	Requirement — Test			Result — Remark		Verdict	
<b>6.8</b>	<b>TABLE: Dielectric strength tests</b>					<b>Form A.18</b>	
4.4.4.1 b)	Conformity after application of SINGLE FAULT CONDITIONS <sup>1</sup>						
6.4	Primary means of protection <sup>2</sup>						
6.6	Connections to external circuits						
6.7	Insulation requirements <sup>2</sup> (see Annex K)						
6.10.2	Fitting of non-detachable MAINS supply cords <sup>1</sup>						
9.2 a) 2)	Eliminating or reducing the sources of ignition within the equipment						
9.4 c)	Limited-energy circuit						
9.6.1	Overcurrent protection basic insulation between MAINS - parts						
	Test site altitude .....			< 2000 m			—
	Test voltage correction factor (see table 10) .....			/			—
Location or references from Forms A.1 and A.14	Clause or sub-clause	Humidity	Working voltage	Test voltage	Comments (NOTE)	Verdict	
		Yes/No	[r.m.s./d.c.]	[r.m.s./peak/d.c.]			
A	6.8.3.1	No	230 rms	1040 rms		Pass	
B	6.8.3.1	No	230 rms	1500 rms		Pass	
C	6.8.3.1	No	230 rms	1500 rms		Pass	
D	6.8.3.1	No	230 rms	1040 rms		Pass	
E	6.8.3.1	No	24 dc	850 rms		Pass	
F	6.8.3.1	No	24 dc	850 rms		Pass	
G	6.8.3.1	No	230 rms	3000 rms	Test not performed because the network isolator complies with IEC 60601-1:2005 + A1:2012 standard requirements for 2MOPP (5 kVac x 1 min. dielectric strength)	Pass	
<sup>1</sup> Record the fault, test or treatment applied before the dielectric strength test. <sup>2</sup> Humidity preconditioning required. NOTE: Test duration may be recorded. Supplementary information: /							

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IEC 61010-1					
Clause	Requirement — Test			Result — Remark	Verdict
<b>10.</b>	<b>TABLE: Temperature Measurements</b>				<b>Form A.26A</b>
10.1	Surface temperature limits – NORMAL CONDITION <del>and / or SINGLE FAULT CONDITION</del>				P
10.2	Temperature of windings – NORMAL CONDITION <del>and / or SINGLE FAULT CONDITION</del>				P
10.3	Other temperature measurements				P
Operating conditions:		Waste treatment cycle used until thermal equilibrium of measured parts/locations temperature values			
Frequency..... :	60 Hz	Test room ambient temperature (ta).... :	29.1 to 29.9 °C		
Voltage..... :	440 V	Test duration..... :	1 h 00 min		
Part / Location	$t_m$ [°C]	$t_c$ [°C]	$t_{max}$ [°C]	Verdict	Comments
Module, Electrical cabinet, internal ambient temperature near Mean Well power supply units	36.00	46.90	50	Pass	TC12
Module, Electrical cabinet, internal ambient temperature (all other components)	35.31	44.51	50	Pass	TC2
Module, vacuum pump motor	65.46	74.66	145	Pass	TC3 Class F
Touch screen display, plastic enclosure	36.28	45.48	85	Pass	TC4
Touch screen display, metal enclosure	32.82	42.02	65	Pass	TC5
Steam chamber door surface	47.51	56.71	65	Pass	TC6
Enclosure, metal panels (near steam chamber door surface)	34.29	43.49	65	Pass	TC7
Module, internal wirings/cables ambient temperature (interconnection wires bundle)	43.97	53.17	70/180	Pass	TC16
Mains wiring box, internal ambient temperature	36.20	45.4	60	Pass	TC10
Steam generator enclosure (reference for internal wirings)	63.18	72.38	180	Pass	TC11
Test room ambient temperature	29.93	---	---	---	TC17
NOTE 1 - $t_m$ = measured temperature $t_c = t_m$ corrected ( $t_m - t_a + 40$ °C or max. RATED ambient) $t_{max}$ = maximum permitted temperature NOTE 2 - see also 14.1 with reference to component operating conditions NOTE 3 - Record values for NORMAL CONDITION and / or SINGLE FAULT CONDITION in this Form use additional form if necessary NOTE 4 - see Form A.26B for details of winding temperature measurements					
Supplementary information: /					

10.	TABLE: Temperature Measurements				Form A.26A
10.1	Surface temperature limits – NORMAL CONDITION and / or SINGLE FAULT CONDITION				P
10.2	Temperature of windings – NORMAL CONDITION and / or SINGLE FAULT CONDITION				P
10.3	Other temperature measurements				P
Operating conditions:		Waste treatment cycle used until thermal equilibrium of measured parts/locations temperature values			
Frequency .....	60 Hz	Test room ambient temperature (ta) ...:	29.9 to 29.9 °C		
Voltage.....	360 V	Test duration .....	1 h 00 min		
Part / Location	$t_m$ [ °C ]	$t_c$ [ °C ]	$t_{max}$ [ °C ]	Verdict	Comments
Module, Electrical cabinet, internal ambient temperature near Mean Well power supply units	37.20	47.30	50	Pass	TC12
Module, Electrical cabinet, internal ambient temperature (all other components)	38.29	48.29	50	Pass	TC2
Module, vacuum pump motor	66.91	76.91	145	Pass	TC3 Class F
Touch screen display, plastic enclosure	36.35	46.35	85	Pass	TC4
Touch screen display, metal enclosure	33.53	43.53	65	Pass	TC5
Steam chamber door surface	51.79	61.79	65	Pass	TC6
Enclosure, metal panels (near steam chamber door surface)	35.22	45.22	65	Pass	TC7
Module, internal wirings/cables ambient temperature (interconnection wires bundle)	45.30	55.30	70/180	Pass	TC16
Mains wiring box, internal ambient temperature	35.67	45.67	60	Pass	TC10
Steam generator enclosure (reference for internal wirings)	63.58	73.58	180	Pass	TC11
Test room ambient temperature	29.94	---	---	---	TC17
NOTE 1 - $t_m$ = measured temperature $t_c = t_m$ corrected ( $t_m - t_a + 40$ °C or max. RATED ambient) $t_{max}$ = maximum permitted temperature NOTE 2 - see also 14.1 with reference to component operating conditions NOTE 3 - Record values for NORMAL CONDITION and / or SINGLE FAULT CONDITION in this Form use additional form if necessary NOTE 4 - see Form A.26B for details of winding temperature measurements					
Supplementary information: /					

TESTED BY: A. Capoferri

DATE: 2024/06/19

TEST EQUIPMENT LIST ITEM: SAF.009, SAF.014, SAF.015, SAF.068

--- END OF TEST REPORT ---