**BUREAU VERITAS**
**Certification**

# ASSING S.p.A.

Via E. Amaldi, 14 - 00015 MONTEROTONDO (RM) – ITALY

**Certified site:**
Via E. Amaldi, 14 - 00015 MONTEROTONDO (RM) – ITALY

*Bureau Veritas Italia S.p.A. certifies that the Full Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of*

# DIRECTIVE 93/42/EEC

*(in accordance with Annex II - excluding paragraph 4)*

*In relation to the following products*

| | |
|---|---|
| Product subcategory : | Imaging devices utilising ionizing radiation |
| Generic group: | Radiological tilting table |
| Model: | HELIOS DRF, HELIOS SFD |
| Class: | IIb |

Reference BV practice: ZIG. N. **9414308**

Original cycle start date: **05 December 2016**

Expiry date of previous cycle: **28 November 2020**

Certification / Recertification Audit date: **13 September 2019**

Certification / Recertification cycle start date: **28 July 2020**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **26 May 2024**

**Certificate No. - Version: IT272133 - 1**

Revision date: **28 July 2020**

***ANDREA FILIPPI– Certification SL Manager***

*This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza, 347-20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370*

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please refer to the website www.bureauveritas.it

Digitally signed by Matei Vasile
Date: 2023.06.29 11:20:15 EEST
Reason: MoldSign Signature
Location: Moldova

# DECLARATION OF CONFORMITY

Manufacturer: Assing S.p.A.
Via E. Amaldi, 14
00015 Monterotondo, Roma, Italy

| Product Name | Model | Classification | Rule |
|---|---|---|---|
| Radiological Tilting Table | Helios DRF | II B | Annex II – excluding paragraph 4, of the Directive 93/42/EEC on Medical Device |
| Radiological Tilting Table | Helios SFD | II B | |

We, hereby declare that we will look after the proper application of the quality system earmarked for design, production and final inspection of the medical equipment stipulated below.
We do assure and declare that the aforementioned products meet requirement of Medical Device Directive 93/42/EEC Annex II – excluding paragraph 4, concerning medical equipment and that we have been familiarized ourselves with a result of design documentation evaluation and that we have been authorized to use "CE" mark with identification number: 1370.
Standard Applied: the applicable section of the following standard for safety and quality were applied: ISO 9001:2015; ISO 13458:2016; CE1370.

NOTIFIED BODY: Bureau Veritas Italia S.p.A.
Via Miramare, 15 – 20126 Milano, Italy
Tel: +39 02 270911 www.bureauveritas.it

CERTIFICATES: ISO 9001:2015 No: IT270542
ISO 13485:2016 No. IT272156-1
CE 1370 No. IT272133 - 1

30.11.2020
MONTEROTONDO / ITALY

Giselda De Silva
General Manager / Assing S.p.A.

ASSING S.P.A.
Via E. Amaldi, 14 - 00015 Monterotondo (RM)
C.F. 06725640582 - P.IVA 01603091008
Tel. 06.90670300
L'Amministratore Delegato
Dott.ssa Giselda De Silva

Bureau Veritas Certification

# ASSING SPA

Via Edoardo Amaldi, 14 - 00015 MONTEROTONDO (RM) - Italy

Certified site:

Via Edoardo Amaldi, 14 - 00015 MONTEROTONDO (RM) - Italy

*Bureau Veritas Italia S.p.A. certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below*

## ISO 9001:2015

*Scope of certification*

**Design and construction of turnkey clean rooms, engine testing rooms and related components. Trade and service oh high technology instrumentation for scientific research, diagnostics and industrial purpose. Design, production, installation and technical assistance of x-ray medical equipment and systems.**

Certificate issued in accordance with the Technical Regulation ACCREDIA RT-05

IAF sector: **19, 28, 29**

| | |
|---|---|
| Original cycle start date: | **16-September-1999** |
| Expiry date of previous cycle: | **04-June-2021** |
| Certification / Recertification Audit date: | **05-May-2021** |
| Certification / Recertification cycle start date: | **24-May-2021** |
| Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: | **04-June-2024** |

Certificate No.: **IT306613** Version: **1** Issue Date: **24-May-2021**

***GIORGIO LANZAFAME - Local Technical Manager***

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 009A

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

Certification body address:

Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia

Certification awarded in conformity with the provisions of ACCREDIA document RT-05

The present certification is to be intended as referred to the general management aspects of the company as a whole and may be used for the purpose of qualification of construction companies according to Art. 84 of the D. Lgs. 50/2016 and subsequent modifications and Anac applicable guidelines

Subject to the continued satisfactory operation, to check this certificate validity please refer to website: http://www.bureauveritas.it/certificate.
Further clarifications regarding the scope of this certificate and the applicability of standard's requirements may be obtained by consulting the organisation at registro.certificati@it.bureauveritas.com

**BUREAU VERITAS**
**Certification**

# ASSING S.p.A.

Via E. Amaldi, 14 – 00015 MONTEROTONDO (RM) - ITALY

**Certified site:**

Via E. Amaldi, 14 – 00015 MONTEROTONDO (RM) - ITALY

*Bureau Veritas Italia S.p.A. certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below*

# EN ISO 13485:2016

*Scope of certification*

Design, production, installation and service of x-ray medical equipment and systems.

Certificate awarded in conformity with the requirements of ACCREDIA DT 02-DC Rev.00

| | |
|---|---|
| Original cycle start date: | **05 December 2016** |
| Expiry date of previous cycle: | **28 November 2020** |
| Certification / Recertification Audit date: | **13 September 2019** |
| Certification / Recertification cycle start date: | **28 July 2020** |

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **28 July 2023**

**Certificate No. - Version: IT272156 - 1**

Revision date: **28 July 2020**

***GIORGIO LANZAFAME – Local Technical Manager***

Certification body address:
Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please refer to the website www.bureauveritas.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 009A

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

Certificate FR12/01144

The management system of

# MED.E.COM s.a.r.l.
# trading as MEDECOM

9 bis - rue de Kerbrat, 29470 Plougastel Daoulas, France

has been assessed and certified as meeting the requirements of

## ISO 13485:2016
## EN ISO 13485:2016

For the following activities

**Design and development, production, sales and servicing of software solutions for digital radiology.**

This certificate is valid from 21 July 2021 until 28 June 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 7. Certified since 29 June 2012

*Expiry date of last certificate: 28 June 2021*
*End date of last recertification audit: 25 May 2021*

Certifié conforme au document
présenté et scellé
Plougastel
19 SEP. 2022
Elodie PICHON
Agent Territorial

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

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