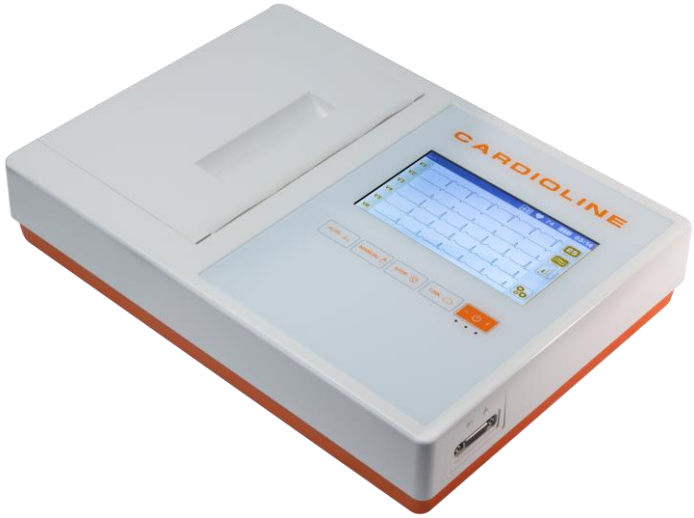
CARDIOLINE

PRODUCT SHEET: ECG200L



Description of product:

The device is a 12-lead, fully diagnostic electrocardiograph which displays, acquires, prints and stores ECG tracings, for adults and children, together with its measurements..
ECG200L is characterized by a useful 7" colour touchscreen display, from which all operations can be easily performed. A smart user interface guides the user through the different steps necessary to acquire the electrocardiogram. Various messages on the screen visually inform the user of the ongoing operations and warn him in case of errors (for example in case of lead fail).
The device is equipped with USB to export the ECG stored in the device memory.
The device can be supplied with the optional 12-lead Glasgow resting ECG interpretation algorithm, with specific criteria by age, sex and race. If this option is enabled, the algorithm provides full ECG interpretation in short or extended form, including infant, pediatric and acute ST elevation myocardial infarction detection.
For further information on the resting ECG interpretation algorithm, see the Guidance for the physician on the application on adults and children (see accessories list).
The device is battery or mains operated.
The printing formats supported include: standard or Cabrera 3, 3+1, 3+3, 6 or 12 channels in automatic mode and 3, 6 or 12 printout channels in continuous mode, as well as printout of the rhythm strip.
It is possible to export the exams on a key or USB to a PC software application named ECGEasyApp.

GENERAL INFORMATION

Product Name	ECG200L
General Name	ECG200L
Product Code	80608070
Manufacturer	Cardioline S.p.A.
	Headquarters Via Linz, 151 38121 Trento Italia
Intended use	ECG200L is a multi-channel, interpretative resting electrocardiograph. The ECG signal is acquired with a 10-wires patient cable and is displayed in real time on a LCD screen integrated in the device. The electrocardiograph can analyse and store the ECG traces, send them to an external peripheral via USB, print the 12 lead ECG in automatic or manual mode by means of its built-in thermal printer. ECG200L is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Physician.

	ECG200L is intended for use in hospitals, in medical clinics and doctor's offices of any size. ▪ The device is indicated for use to acquire, analyse, display and print electrocardiograms. ▪ The device is intended to provide the physician with an automatic interpretation of the ECG to be reviewed by a physician. ▪ The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis. ▪ The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data. ▪ The device is indicated for use on adult and pediatric populations. The device is not intended to be used as a vital signs physiological monitor.
Year marketed	2018

TECHNICAL SPECIFICATIONS	
ECG Acquisition	
ECG channels	12-lead (I, II, III, aVR-L-F, V1-6)
Patient Cable	Standard 15D connector, 10 wires patient cable
CMRR	> 100dB
Input impedance	100MΩ
A to D converter	16 bit, 32000 samples/second/channel
Sampling rate of the input stage	32000 samples/second/channel
Sampling rate for signal analysis	500 samples/second/channel
A/D conversion	16 bit
Output Data Resolution	5 µV/LSB
Dynamic Range	+/- 325 mV
Bandwidth	Performances equivalent to 0,05-150 Hz
Pacemaker detection	Hardware detection coupled with convolution digital filtering
Defibrillation Protection	AAMI/IEC standards
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Acquisition Mode	Automatic (12 leads), Manual (3/6/12 leads), STAT (12 leads), Rhythm (1 Lead for 3 minutes or 3 Leads for 1 minute)
Lead Configuration	Standard, Cabrera
Processing	
Pace detection	Hardware detection in compliance with the requirements 60601-2-25

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Lead fail detection	Independent on all leads. “Torso” function that allows you to view the disconnected electrodes in red and those correctly connected in green.
Heart Rate Meter	30 - 300 bpm
Filters	Linear phase digital diagnostic high-pass filter (according to 60601-2-25 2nd ed.) 50/60 Hz AC interference adaptive digital filter Digital low pass filters at 25/40 Hz, for display and printing only
ECG Measurements	All leads, average, corrected HR Average RR PR Interval QRS duration QT interval and QTc interval, with Hodges, Bazzet and Fridericia’s formula max R[V5]or[V6] and S[V1] Sokolow-Lyon Index P, R, T axis.
ECG Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI
ECG Interpr. Data input	Sex, age
Storage	50 ECG
Available languages	Brazilian, Czech, Croatian, Dutch, French, English, Italian, Polish, Portuguese, Romanian, Russian (with Russian keyboard), Serbian, Spanish, German, Turkish, Hungarian
Autotest	The device performs an auto-test of its internal electronic functions at every start up.
Processing Options	
Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI (optional)
Supported export formats	
SCP	Standard
PDF	Through a dedicated application for files management on Personal Computer
Connectivity	
USB	Standard
Display	
Display Type	7” TFT Backlit Color LCD with Capacitive Touch Panel
Display resolution	800x480
Display data	3/6/12 leads real-time
Display formats	12x1, 6x2, 6x1, 3x1
Keyboard	
Keyboard Type	Touchscreen plus functional dedicated keys
Dedicated Keys	AUTO, MANUAL, STOP, LINK
Printer	
Technology	216 mm Thermal printhead
Resolution	8 dots/mm
Paper type	Thermal paper: roll 210x3000 mm – z-fold A4 295x210mm – letter 280x216mm

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Sensitivity/Gain	5, 10, 20 mm/mV
Auto print speed	5, 10, 25, 50 mm/s
Auto print	3, 3+1, 6, 12 channels; Standard or Cabrera
Manual print speed	5, 10, 25, 50 mm/s
Manual Print	3/6/12 channels; Standard o Cabrera
Rhythm Print	1 minute 3 leads; 3 minutes 1 lead HR Trend HR statistics
Printing formats	12x1, 6x2, 6+6, 3x4, 3x4+1, 3x4+3
Calibration signal	Yes, 1 mV
Lead marker	Yes, before each lead trace
USB External Peripherals	
External data storage	USB memory stick (for data export)
Electrical Characteristics	
Power source	Internal power supply and internal rechargeable battery
Input Voltage	100-240 Vac
Input Current	1.5-0.75 A
Input frequency	50/60 Hz
Rated Output	60 W, 18 V, 3.34 A
Protection Class	I
Battery Type	NiMH
Battery Duration	more than 500 ECGs – more than 6h
Battery Charging Time	4 hours to 85% full capacity
Physical Characteristics	
Dimensions	413x295x80 mm
Weight	4,17 Kg
Shipping container	580X470X280 mm – 7Kg
Operating Environmental Specifications	
Temperature	+10°C - +40°C
Humidity	50% - 90%
Pressure	700hPa - 1060hPa
Storage Environmental Specifications	
Temperature	5°C - +40°C
Humidity	20% - 90%
Pressure	700hPa - 1060hPa

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REGULATORY AND SAFETY	
Classification according MDD 93/42/CEE	
Class	Class IIa
Rationale	rule 10 annex IX 93/42/EEC Directive and its amendments
Notified body	TUV (1936)
Classification according to FDA regulation	
Classification:	In progress
Product Code:	In progress
Review Panel:	In progress
Regulation Number:	In progress
Classification according to IEC 60601-1 - Electrical Safety	
Protection against electric shock:	Internal power - class I
Applied parts:	type CF – defibrillation-proof
Protection against harmful ingress of water or particular matter:	IPX0
Method(s) of sterilization:	NA (not intended to be sterilized)
Suitability for use in an oxygen rich environment:	No
Mode of operation:	continuous operation
Classification according to IEC 60601-1-2 - Electro Magnetic Compatibility	
Group	1
Class	B
Performances	
Standard	EN 60601-2-25:2011
Other classifications	
GMDN	110407 - Electrocardiographs, Multichannel, Interpretive
CND	Z12050302 - ELETTROCARDIOGRAFI PER DIAGNOSI AVANZATA
RDM (Registration number in Italy)	1760532
Applicable Standards	
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041	Information supplied by the manufacturer of medical devices
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)

EN ISO 14971	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 62304	Medical device software - Software life-cycle processes
EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366	Medical devices - Application of usability engineering to medical devices
EN 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs

PRODUCT CODES AND ACCESSORIES	
Accessories	
869060001	Set of 4 Peripheral ECG electrodes clamp Ag/AgCl
63030106	Set of 4 peripheral ECG electric clamp Ag/AgCl
63030107	Set of 4 peripheral ECG electric clamp pediatric Ag/AgCl
828030001	Set of 6 chest ECG electric suction type Ag/AgCl
63050025 63050142	ECG patient cable IEC, 10 lead, plug 4 mm
63050068 63050143	ECG patient cable AHA, 10 lead, plug 4 mm
63050108 63050130	ECG patient cable IEC, 10 lead, snap
63050109 63050141	ECG patient cable AHA, 10 lead, snap
63050032	ECG patient cable IEC-10 CLIP 4 mt
M-00-S	Disposable electrodes ECG, snap, 50 pcs
66030040C	Disposable electrodes ECG, tab, 100 pcs; pack of 10
N-10-A	Disposable electrodes ECF neonatal, 25 pcs
SU-00-A	Disposable electrodes ECG banana, 60 pcs
63090236	Set of 10 snap adapters for 4 mm plug
66020008	Adapters for tab and button electrodes for 4 mm plug, 10 pcs
66010052S	Z-Fold paper A4 210x295mm, 180 sheeets, 10 pcs
66010053S	Z-Fold paper Letter 216x280mm, 180 sheeets, 10 pcs
63090713	ECG200+/S/L trolley II Edition hospital grade

CARDIOLINE

ECG100L

General Information

Product Name	ECG100L
General Name	ECG100L
Product Code	80508097
Manufacturer	Cardioline Spa Registered Office and Factory: Via Linz, 151 38121 Trento Italy Sales Office: Via F.lli Bronzetti, 8 20129 Milan Italy
Device Description	The device is a 12-lead, fully diagnostic PORTABLE electrocardiograph which displays, acquires, prints and stores ECG tracings, for adults and children, together with its measurements.. ECG100L is characterized by a useful 5" colour touchscreen display, from which all operations can be easily performed. A smart user interface guides the user through the different steps necessary to acquire the electrocardiogram. Various messages on the screen visually inform the user of the ongoing operations and warn him in case of errors (for example in case of lead fail). The device is equipped with USB to export the ECG stored in the device memory. The device can be supplied with the optional 12-lead Glasgow resting ECG interpretation algorithm, with specific criteria by age, sex and race. If this option is enabled, the algorithm provides full ECG interpretation in short or extended form, including infant, pediatric and acute ST elevation myocardial infarction detection. For further information on the resting ECG interpretation algorithm, see the Guidance for the physician on the application on adults and children (see accessories list). The device is battery or mains operated. The printing formats supported include: standard or Cabrera 3, 3+1, 3+3 or 6 channels in automatic mode and 3 or 6 channels rhythm strip printing. It is possible to export the exams on a key or USB to a PC software application named ECGEasyApp.

Technical Specifications

ECG Acquisition

ECG channels	12-lead (I, II, III, aVR-L-F, V1-6)
Patient Cable	Standard 15D, 10 wires patient cable
CMRR	> 100dB
Input impedance	100MΩ
A to D converter	16 bit, 32000 samples/second/channel
Sampling rate of the input stage	32000 samples/second/channel
Sampling rate for signal analysis	500 samples/second/channel

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A/D conversion	16 bit
Output Data Resolution	5 µV/LSB
Dynamic Range	+/- 325 mV
Bandwith	0,05-150 Hz
Pacemaker detection	Hardware detection coupled with convolution digital filtering
Defibrillation Protection	AAMI/IEC standards
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Acquisition Mode	Automatic (12 leads), Manual (3/6 leads), Stat (12 leads)
Lead Configuration	Standard, Cabrera
Processing	
Pace detection	Hardware detection in compliance with the requirements 60601-2-25
Lead fail detection	Independent on all leads
Heart Rate Meter	30 - 300 bpm
Baseline stabilization	Diagnostic fully digital high pass filter
AC Filter	50/60 Hz adaptive digital filter
Filters	Digital low pass filters at 25/40 Hz, for display and printing only
ECG Measurements	All leads, average, corrected HR Average RR PR Interval QRS duration QT and QTc (Hodges formula) intervals QTc Bazett interval QTc Fridericia interval max R[V5];[V6] and S[V1] Sokolow-Lyon Index P, R, T axis.
ECG Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI (Optional)
ECG Interpr. Data input	Sex, age
Storage	50 ECG
Available languages	Czech, Croatian, French, English, Italian, Polish, Portuguese, Romanian, Russian, Serbian, Spanish, German, Turkish, Hungarian
Autotest	The device perform an auto-test of its internal electronic functions at every start up.
Processing Options	
Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI
Supported export formats	
SCP	Standard
PDF	Through a dedicated application for files management on Personal Computer
Connectivity	
USB	Standard
Display	

Display Type	5” TFT Backlit Color LCD with Resistive Touch Panel
Display resolution	800x480
Display data	3/6/12 leads realtime
Display formats	6x2, 6x1, 3x1
Keyboard	
Keyboard Type	Touchscreen plus functional dedicated keys
Dedicated Keys	AUTO, MANUAL, STOP, LINK
Printer	
Technology	108 mm Thermal printhead
Resolution	8 dots/mm
Paper Type	thermal paper roll 100x2000 mm
Sensitivity/Gain	5, 10, 20 mV/mm
Auto print speed	5, 10, 25, 50 mm/s
Auto print	3, 3+1, 6 channels; Standard or Cabrera
Manual print speed	5, 10, 25, 50 mm/s
Manual Print	3/6 channels; Standard o Cabrera
Printing formats	6x2, 3x4, 3x4+1, 3x4+3
Calibration signal	Yes, 1 mV
Lead marker	Yes, before each lead trace
USB External Peripherals	
External data storage	USB memory stick (for data export)
Electrical Characteristics	
Power source	External power supply or internal rechargeable battery
Power supply	Medical grade - Mod. AFM60US18 - XP Power Limited
Input Voltage power supply	100-240 Vac
Input Current power supply	1.5-0.9 A
Input frequency power supply	50/60 Hz
Rated Output power supply	60 W, 18 V, 3.34 A
Protection Class power supply	I
Degree of Protection power supply	IP20
Battery Type	NiMH
Battery Duration	more than 500 ECGs – more than 6h
Battery Charging Time	4 hours to 85% full capacity
Physical Characteristics	
Dimensions	270x190x60 mm
Weight	1,48 Kg
Shipping container	360x360x250 mm - 4Kg

Operating Environmental Specifications

Temperature	+10°C - +40°C
Humidity	20% - 95%
Pressure	700hPa - 1060hPa

Storage Environmental Specifications

Temperature	0°C - +40°C
Humidity	20% - 95%
Pressure	700hPa - 1060hPa

Regulatory and Safety

Classification according MDD 93/42/CEE

Class	Class IIa
Rationale	rule 10 annex IX 93/42/EEC Directive and its amendments
Notified body	TUV (1936)

Classification according to FDA regulation

Classification:	In progress
Product Code:	In progress
Review Panel:	In progress
Regulation Number:	In progress

Classification according to IEC 60601-1 - Electrical Safety

Protection against electric shock:	IP (internal power ME) - class I on the external AC/DC
Applied parts:	type CF – defibrillation-proof
Protection against harmful ingress of water or particular matter:	IPX0
Method(s) of sterilization:	NA (not intended to be sterilized)
Suitability for use in an oxygen rich environment:	No
Mode of operation:	continuous operation

Classification according to IEC 60601-1-2 - Electro Magnetic Compatibility

Group	1
Class	B

Performances

Standard	EN 60601-2-25:2011

Other classifications

GMDN	110407 - Electrocardiographs, Multichannel, Interpretive
CND	Z12050302 - ELETTROCARDIOGRAFI PER DIAGNOSI AVANZATA
RDM (Registration number in Italy)	1614799

Applicable Standards

EN 980	Symbols for use in the labelling of medical devices
EN 1041	Information supplied by the manufacturer of medical devices
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN ISO 14971	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 62304	Medical device software - Software life-cycle processes
EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366	Medical devices - Application of usability engineering to medical devices
EN 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs

Product codes and accessories

Accessories

63030105	4 Peripheral ECG electrodes clamp AG/ agcl
63030106	Set of 4 peripheral ECG electric clamp Ag/Agl
63030107	4 peripheral ECG electric clamp pediatric
63030163	6 chest ECG electric suction type Ag/agcl
63050025	ECG patient cable IEC, 10 lead, plug 4 mm
63050068	ECG patient cable AHA, 10 lead, plug 4 mm
63050108	ECG patient cable IEC, 10 lead, snap
63050109	ECG patient cable AHA, 10 lead, snap
69701886	Battery pack
63050032	IEC-10 CLIP 4 mt PATIENT CABLE
66030031C	Disposable electrodes ECG, snap, 50 pics
66030034C	Disposable electrodes ECG, tab, 100 pics
66030036C	Disposable electrodes ECG neonatal, 25 pics
66030037C	Disposable electrodes ECG banana, 60 pics
63090236	Set of 10 snap adapters for 4 mm plug
66010055	Thermal paper roll 100x2000 mm
63090689	ECG100+/S trolley

Certificato di conformità CE

EC Certificate of Conformity

TÜVRheinland®

Sistema completo di garanzia di qualità secondo direttiva 93/42/CEE allegato II escluso punto 4

EC Directive 93/42/EEC Annex II, excluded clause 4 Full Quality Assurance System Medical Devices

Certificato n°: **HD 60146561**

Registration No:

Fabbricante: **Cardioline S.p.a.**

Manufacturer:

Sede legale: **Via Linz, 151**

Registered Headquarter: **38121 Trento (TN) - Italia**

Sede operativa: **Via Linz, 151**

Operational Headquarter: **38121 Trento (TN) - Italia**

Scopo: **Dispositivi di monitoraggio di parametri fisiologici vitali /**

Scope: *Monitoring devices of vital physiological parameters*

Software / *Software*

(Vedere allegato tecnico al presente Certificato per tipologie, modelli e codici)

(*See the attachment for typologies, models and codes designation)*

L'organismo notificato dichiara che il Sistema di qualità stabilito ed applicato dalla società sopra specificata soddisfa i requisiti dell'allegato II, articolo 3 della suddetta direttiva. Questa approvazione è soggetta a sorveglianza periodica, così come definita nell'allegato II, articolo 5 della suddetta direttiva e può essere utilizzata congiuntamente alla dichiarazione di conformità redatta dal fabbricante. / The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5, of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

L'organismo notificato/ ***Notified Body***

Data di emissione/*Issue date*: **15/04/2020**

Data di ultima modifica/*Last revision date:* **15/04/2020**

Data di scadenza/*Expiry date:* **26/05/2024**

Paolo Caglio

TÜV Rheinland Italia S.r.l. Certification Body

TÜV Rheinland Italia S.r.l. - Via Mattei, 3 - 20010 - Pogliano Milanese (MI)

Autorizzata dal Ministero della Salute e dal Ministero dello Sviluppo Economico

Accredited by Ministry of Health and by Ministry of Economic Development

Organismo notificato con il numero 1936 presso la Commissione Europea

Notified under No. 1936 to the EC Commission

CE La marcatura CE può essere apposta esclusivamente se vengono soddisfatti i requisiti di tutte le direttive CE applicabili CE

The CE marking may be used if all relevant and effective EC Directives are complied with

Allegato tecnico al Certificato n° HD 60146561

Attachment to the certificate:

TÜVRheinland®

Fabbricante/*Manufacturer:* **Cardioline S.p.a.**

Scopo/*Scope:* **Dispositivi di monitoraggio di parametri fisiologici vitali /** *Monitoring devices of vital physiological parameters*

Tipologia/ *Typology:* **Holter abpm /** *Abpm Holter*

Modello/ *Model:*

Walk200b, bp one +

Tipologia/ *Typology:* **Holter ECG /** *ECG Holter*

Modello/ *Model:*

Clickholter; Walk400h, click holter+

Tipologia/ *Typology:* **Unità di acquisizione ECG /** *ECG Acquisition Units*

Modello/ *Model:*

HD+ ; CLICKECG-HD

Tipologia/ *Typology:* **Elettrocardiografi /** *Electrocardiograph*

Modello/ *Model:*

ECGxxx (z) (+)

Legenda/ *Key.*

- **xxx : dimensione stampante** / *printer size*
- **(z): interfaccia** / *interface*
- **(+) : connettività internet** / *internet connection*

L'organismo notificato
Notified Body

TÜV Rheinland Italia S.r.l. TÜVRheinland Certification Body

Data di ultima modifica: **15/04/2020**
Last revision date:

Tipologia/ *Typology:* **Sistemi elettrocardiografi /** *Electrocardiographic systems*

Modello/ *Model*

touchECG System

Codice/Code

KTCH$XXYZ-@

Legenda/ *Key:*

- **$= sistema operativo** / *Operating system (Windows or Android)*
- **XX=tipo di computer** / *kind of computer,*
- **Y= tipologia di carrello** / *kind of cart,*
- **Z= altri accessori** / *other accessories,*
- **@=Elettrodi, cavi paziente, caratterizzazioni estetiche** / *Electrodes, patient cable and esthetical customizations*

Tipologia/ *Typology:* **Sistema per l'analisi di sforzo cardiavascolari/** *Cardiovascular stress test system*

Modello/ *Model*

Cubestress System

Codice/Code

KSSXYYZWJ-@

Legenda/ *Key*

- **X=tipologia di sistema** / *system type,*
- **YY=tipo di computer** / *kind of computer,*
- **Z= tipologia di carrello** / *kind of cart,*
- **W= tipologia di stampante** / *kind of printer,*
- **J= accessori** / *other accessories,*
- **@=Caratterizzazioni estetiche** / *esthetical customizations*

L'organismo notificato
Notified Body

TÜV Rheinland Italia S.r.l. TÜVRheinland® Certification Body

Data di ultima modifica: **15/04/2020**
Last revision date:

Scopo/*Scope:* **Software /** *Software*

Tipologia/ *Typology:* **Software elettrocardiografico /** *Electrocardiographic software*

Modello/ *Model*

touchECG rel. 3.xy Ed: z

Codice/Code

81019579 – for Windows
81019582 – for Android

Tipologia/ *Typology:* **Sistemi software di importazione, analisi, refertazione e archiviazione esami Holter ECG /** *Software systems for importing, analyzing, reporting and archiving Holter ECG exams*

Modello/ *Model*

Cubeholter WS Rel. 3.xy Ed: z

Codice/Code

85039510

Modello/ *Model*

Cubeholter Web Rel. 3.xy Ed: z

Codice/Code

85039520

Legenda/ *Key*

x= versioni minori / minor changes
y= correzioni / bug fix release

Se xy=00, è idenfiticato con 0 / If xy = 00, it's identified as 0

z: contenuto della configurazione / content of the distribution media

L'organismo notificato
Notified Body

TÜV Rheinland Italia S.r.l. TÜVRheinland Certification Body

Data di ultima modifica: **15/04/2020**
Last revision date:

Tipologia/ *Typology:* **Software di archiviazione, misurazione e refertazione esami /**
Software for exams archiving, measurement and review

Modello/ *Model:*

ECGWebApp Rel. 2.xy Ed: z

Codice/Code:

81019560

Tipologia/ *Typology:* **Sistemi software di monitoraggio /** *Monitoring systems software*

Modello/ *Model:*

CUBE SUITE; Cubeabpm; Cubestress Lite; Cubestress Rel. 1.4 .x.y Ed: z

Modello/ *Model:*

Cubestress Rel. 4.xy Ed: z

Codice/Code:

85050100

Legenda/ *Key:*

x= versioni minori / minor changes
y= correzioni / bug fix release

Se xy=00, è idenfiticato con 0 / If xy = 00, it's identified as 0

z: contenuto della configurazione / content of the distribution media

L'organismo notificato
Notified Body

Data di ultima modifica: **15/04/2020**
Last revision date:

CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

Cardioline S.p.a.

Via Linz, 151

IT - 38121 Trento (TN)

has established and applies a quality management system
for the following scope:

Design, manufacturing, trading, installation and servicing of systems and electrical medical devices and software for cardiology.

Through an Audit, Report No. 7968894070LM18, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2016

Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 0631503**.

This Certificate is valid from 2021-04-25 to 2024-04-24.

The reference date for all the next audits is (day-month): 12-06.

Milan, 2021-04-25. First Certification: 2012-06-13

The certification responsible: Elena Re
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC, 90/385/EEC or 98/79/EC have been fulfilled.

ACCREDIA
SGQ N° 083 A

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

TÜVRheinland CERTIFIED
Management System
EN ISO 13485:2016
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ID 9105082907

www.tuvitalia.com

TÜVRheinland®