TÜV Rheinland Italia S.r.l.
Sicurezza e Qualità Prodotto

TÜV Rheinland Italia S.r.l.
Via Mattei 3
20005 Pogliano Milanese (MI)
Italia

Via del Faggiolo 1/12
40132 Bologna
Italia

Cardioline SpA
Via Linz 151 – 38121 Trento (TN)
Attention:
Dott. Emanuele Ercoli

Date: 2024/04/17

Object: Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

---

Dear Dott. Ercoli,

This letter confirms that, TUV RHEINLAND ITALIA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1936 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Cardioline SpA
Via Linz 151 – 38121 Trento (TR)

The devices covered by the formal application and the written agreement mentioned above are identified in the Table below

The table identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)

TÜV Rheinland Italia S.r.l.
Sede Legale ed operativa
Membro del Gruppo
TÜV Rheinland

Via Mattei, 3
20005 Pogliano Milanese (MI)

Tel: +39.02.939.687.1
Fax: +39.02.939.687.23
E-mail:informazioni@it.tuv.com
Web:www.tuvitalia.com

Capitale sociale
EURO 51.000,00 int. versato
C.C.I.A.A. Milano No. 1535451
Registro Milano No. 214918
CF e IVA 12184570153

- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Devices covered by this letter, and for which the NB is responsible for appropriate surveillance of the corresponding devices under the applicable Directive, and identified on the basis of the indications provided in the MDR application received:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ECG100+, ECG200+, ECG100S, ECG200S BASIC UDI-DI: 0805673265011000024X	Class IIa	ECGxxx (z) (+) xxx: printer size (z): interface (+): internet connectivity	HD 60146561 Annex II excl. point 4 TUV Rheinland Italia S.r.l. CE1936
ECGWebApp Rel. 3.x.y. Ed.:z BASIC UDI-DI: 0805673265012000015A	Class IIa	ECGWebApp Rel. 2.x.y. Ed.:z Code: 81019560	HD 60146561 Annex II excl. point 4 TUV Rheinland Italia S.r.l. CE1936
Cubeholter (Cubeholter WS/ Cubeholter Web) Rel. 4.x.y Ed. z BASIC UDI-DI: 0805673265012000045G	Class IIa	Cubeholter WS Rel. 3.x.y Ed. z Code: 85039510 Cubeholter Web Rel. 3.x.y Ed. z Code: 85039520	HD 60146561 Annex II excl. point 4 TUV Rheinland Italia S.r.l. CE1936
Cubestress Rel. 6.x.y Ed. Z BASIC UDI-DI: 0805673265012000035E	Class IIa	Cubestress Rel. 5.x.y Ed. z Code: 85050100	HD 60146561 Annex II excl. point 4 TUV Rheinland Italia S.r.l. CE1936
ECG100L ECG200L BASIC UDI-DI: 0805673265011000014V	Class IIa	ECGxxx (z) (+) xxx: printer size (z): interface (+): internet connectivity	HD 60146561 Annex II excl. point 4 TUV Rheinland Italia S.r.l. CE1936

TÜV Rheinland Italia S.r.l.
Sede Legale ed operativa
Membro del Gruppo
TÜV Rheinland

Via Mattei, 3
20005 Pogliano Milanese (MI)

Tel: +39.02.939.687.1
Fax: +39.02.939.687.23
E-mail:informazioni@it.tuv.com
Web:www.tuvitalia.com

Capitale sociale
EURO 51.000,00 int. versato
C.C.I.A.A. Milano No. 1535451
Registro Milano No. 214918
CF e IVA 12184570153

HD+ R2: HD+ 12 CLICKECG-HD12 EC Sense HD+12 HD+ 15 CLICkECG-HD15 EC Sense HD+15 BASIC UDI-DI: 08056732650110000453	Class IIa	HD+ CLICKECG–HD HD+ 12 CLICKECG–HD12 EC Sense HD+12 HD+15 CLICKECG–HD15 EC Sense HD+15	HD 60146561 Annex II excl. point 4 TUV Rheinland Italia S.r.l. CE1936
touchECG Rel. 5.x.y Ed. z BASIC UDI-DI: 080567326501200025C	Class IIa	touchECG Rel. 4.x.y Ed. Z Code ref.: 81019579 – for Windows 81019582 – for Android	HD 60146561 Annex II excl. point 4 TUV Rheinland Italia S.r.l. CE1936
Walk400h Clickholter click holter+ BASIC UDI-DI: 080567326501100034Z	Class IIa	N/A	HD 60146561 Annex II excl. point 4 TUV Rheinland Italia S.r.l. CE1936

This letter does not cover all devices present on HD certificate 60146561, but only those mentioned in the table.

TUV RHEINLAND ITALIA (n.1936)

Lisa Menarini
Project Manager
Firmato digitalmente da Lisa Menarini

Annex:
Certificate No. HD 60146561
issued by TUV Rheinland Italia S.r.l. (Notified Body CE1936)
Issue date: 2020/04/15
Expiry date: 2024/05/26

TÜV Rheinland Italia S.r.l.
Sede Legale ed operativa
Membro del Gruppo
TÜV Rheinland

Via Mattei, 3
20005 Pogliano Milanese (MI)

Tel: +39.02.939.687.1
Fax: +39.02.939.687.23
E-mail:informazioni@it.tuv.com
Web:www.tuvitalia.com

Capitale sociale
EURO 51.000,00 int. versato
C.C.I.A.A. Milano No. 1535451
Registro Milano No. 214918
CF e IVA 12184570153