CARDIOLINE

your profession our mission

walk200b

walk200**b** is a blood pressure holter recorder lasting 24 hours or more. **walk**200**b** complain with the CARDIOLINE® sw. **Cube**abpm (see the dedicated docs).

walk200**b** is a recorder easy to use, light and compact to maximize the patient comfort.

The features which distinguish **walk**200**b** are:

- display LCD to visualize the measured values and service messages, functionality disabled via software;
- connectivity to PC based on bluetooth standard technology;
- self-adapting algorithm to control the cuff pressure;
- event marker function and start/stop wake up/sleep periods;
- limited size and noiseless pump.

walk200b

CE
0476

Cardioline S.p.A.
Via [illegible] 38/A
Via F[illegible]etti, 8
40126 Bologna (BO) Italy
20129 Milano (MI) Italy
info@cardioline.it
tel.+39 02 94750470
www.cardioline.it
fax +39 02 94750471

Sales office:

CARDIOLINE

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Technical features

Feature	*Description*
Pressure measurement range:	
Systolic	60 to 290 mmHg
Diastolic	30 to 195 mmHg
Accuracy	± 3 mmHg in the range indicated
Static pressure range	0 to 300 mmHg
Pulse range	30 to 240 beats per minutes
Method	oscillometric
Measurement intervals	0,1,2,4,5,6,12 or 30 measurements per hour
Monitoring protocol	2 modifiable interval groups
Storage capacity	300 measurements
Battery capacity	> 300 measurements
Operating temperatures	+10°C to +40°C
Operative humidity	15% to 90%
Storage environment	-20°C to 50°C and 15% to 95% humidity
Dimensions	128 x 75 x 30 mm
Weight	approx 240 g including batteries
Power supply	2 Ni-MH batteries each 1,2 V and 1500 mAh (AA, Mignon) or 2 alkaline 1,5 V batteries(AA, Mignon)
Interfaces	Bluetooth (Class 1 / 100 m)

walk200b

CE 0476

Cardioline S.p.A. Via A. Zanolini, 38/A 40126 Bologna (BO) Italy info@cardioline.it www.cardioline.it
Sales office: Via F.lli Bronzetti, 8 20129 Milano (MI) Italy tel.+39 02 94750470 fax +39 02 94750471

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: 2024/04/18

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 (TN)

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

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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**
CubeABPM Rel. 2.x.y Ed: z BASIC UDI-DI: 0805673265012000055J Code ref.: 81019557	Class IIa	Cubeabpm Rel. 1.x.y Ed: z Code ref.: 81019557	HD 60146561 Annex II excl. point 4 TUV Rheinland Italia S.r.l. - CE 1936
Walk200b bp one + BASIC UDI-DI: 08056732650110000555 Code ref.: 87018305 87018307 87019305 87019308 87019310	Class IIa	Walk200b bp one +	HD 60146561 Annex II excl. point 4 TUV Rheinland Italia S.r.l. CE1936
EasyApp Rel. 2.x.y Ed: z BASIC UDI-DI: 0805673265012000065L Code ref.: 81019594	Class IIa		NA (device in class I MDD)
touchECG System BASIC UDI-DI: 0805673265013000025R Code ref.: KTCH$XXYZ-@ $ = Operative system (Windows or Android)	Class IIa	N/A	HD 60146561 Annex II excl. point 4 TUV Rheinland Italia S.r.l. CE1936

TÜV Rheinland Italia S.r.l.
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XX= kind of computer Y= kind of cart Z= other accessories @= electrodes, patient cables, aesthetic characterization			
Cubestress System BASIC UDI-DI: 0805673265013000015P Code ref.: KSSXYYZWJ-@ X= system type YY= kind of computer Z= kind of cart W= kind of printer J=accessories/other accessories @= aesthetic characterization	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.
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TÜV Rheinland Italia S.r.l.
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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

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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.

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- 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)

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- 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

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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

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CF e IVA 12184570153

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
www.tuv.com
ID 9105082907

www.tuvitalia.com

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