Document no.: 02910	**Effective Date:** 2024-07-10	**Version:** 1
Author: Andreas Stochholm; Louise Flintegaard Ehlert	**Approver:** Andreas Stochholm; Louise Flintegaard Ehlert	**Reviewer:** Andreas Stochholm

EU DECLARATION OF CONFORMITY

For the

C3+ Holter Monitor 50002

According to Medical Devices Regulation (EU) 2017/745

Manufacturer: Cortrium ApS
Erik Husfeldts Vej 7
DK-2630 Taastrup, Denmark
SRN: DK-MF-000007827

Declares that the following Medical Device with the product number:

Cortrium C3+ Holter Monitor (50002)

is in conformity with the MDR – Medical Devices Regulation (EU) 2017/745

Classification: IIa – MDR Rule: 10

Reference to other CS:

DS/EN 60601-1-1	Safety Requirements for Medical Electrical Systems
DS/EN 60601-1-2	Electromagnetic Disturbances
DS/EN 60601-1-11	Home Healthcare Environment
DS/EN 60601-2-47	Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
EN 301 489-17 V3.1.1	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17
EN 300 328 V2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band

As Medical Ambulatory ECG Device

UDI-ID
Basic UDI-DI: 5745000379HolterMonitorVN
EMDN Code: Z12050403 - ECG HOLTER RECORDERS

Intended Use
The C3+ is an ambulatory ECG recorder, intended for recording three-channel ECG for up to 7 days. The C3+ is intended for use in both healthcare and home environments. During use, the C3+ continuously records and stores ECG signals and motion data directly in the internal memory.

Additionally, the C3+ has a built in Bluetooth module for streaming live data to a mobile app in order for the healthcare personnel to visually verify signal quality of the ECG (Manual for Mobile app can be found on www.cortrium.com).

Data recorded by the device can be analysed by other processing software to provide reports. This software can be either third party or designed, maintained and/or owned by Cortrium. The C3+ hardware has no capacity for automatic ECG analysis and consequently no capacity for automatically generating alerts to potentially critical cardiac conditions

Document no.: 02910	**Effective Date:** 2024-07-10	**Version:** 1
Author: Andreas Stochholm; Louise Flintegaard Ehlert	**Approver:** Andreas Stochholm; Louise Flintegaard Ehlert	**Reviewer:** Andreas Stochholm

Picture:

Sole responsibility of the manufacturer:
It is ensured that it is under the manufacture's sole responsibility that the medical product Cortrium C3+ Holter Monitor (50002) to which this Declaration of Conformity relates, is in conformity with and meet the provisions of MDR – Medical Devices Regulation (EU) 2017/745, which apply to them and covered by the CE-mark from the Notification Body.

Notify Body:

TÜV SÜD
Product Service GmbH
address: Ridlerstraβe 65
80339 Munich Germany
Notified Body number: **0123**

Risk Class:
The Medical Device, Cortrium C3+ Holter Monitor, has been classified as Class IIa, rule 10, according to Annex IX and is in conformity with the essential requirements and provisions of the Medical Devices Regulation (EU) 2017/745 concerning medical devices (MDR).

EU Quality Management System Certificate (MDR) (CE-mark): G10 098327 0006 Rev. 00

Cortrium has certified a Quality Management System in compliance with the requirements of EN ISO 13485:2016 from the Notified Body TÜV SÜD.

ISO 13485:2016 certificate:	Q5 098327 0003 Rev. 03
valid until:	2027-03-18

Cortrium applies to the obligations of its Quality Management System for the Medical Device: Cortrium C3+ Holter Monitor (50002).

Document no.: 02910	**Effective Date:** 2024-07-10	**Version:** 1
Author: Andreas Stochholm; Louise Flintegaard Ehlert	**Approver:** Andreas Stochholm; Louise Flintegaard Ehlert	**Reviewer:** Andreas Stochholm

This declaration of conformity is issued under the sole responsibility of the manufacturer.

This declaration is valid until 2029-06-24

Taastrup, 2024-06-26

PRRC / CTO
Andreas Stochholm

On behalf of CEO of Cortrium ApS
Philippe W. Jørgensen

History of Revision	
01	First version with approved MDR certificate. With Basic UDI-DI Registered in EUDAMED. Updated according to Anex IV

Signatures:

Controlled Document Approved:	I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.
Name:	**Louise Flintegaard Ehlert** **cortrium.com\lfe**
Electronically Signed in SimplerQMS	2024-07-05 06:46:45 (UTC+00:00) Timestamp

Controlled Document Approved:	I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.
Name:	**Andreas Stochholm** **cortrium.com\as**
Electronically Signed in SimplerQMS	2024-07-10 07:04:01 (UTC+00:00) Timestamp