

[Effective]

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Approver: Erik S. Poulsen; Louise  
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Reviewer:

## DECLARATION OF CONFORMITY with the Medical Device Directive (MDD)

We, as the **Manufacturer**, declare

**Cortrium ApS**  
**Erik Husfeldts Vej 7**  
**DK-2630 Taastrup, Denmark**

that the following Medical Device with the product number 50002

**Cortrium C3+ Holter Monitor**

**is in conformity with the Medical Device Directive (MDD)**

**Classification: IIa - MDD Rule: 10**

as

**Three-channel Ambulatory Electrocardiography ECG medical device**

We ensure under our 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 EC Directive 93/42/EEC (MDD), as amended per MDD 2007/47/EEC, which apply to them and covered by the CE-mark from the Notification Body:

**TÜV SÜD**

Product Service GmbH  
address: Ridlerstraße 65  
80339 Munich Germany  
Notified Body number: **0123**

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 Council Directive 93/42/EEC concerning medical devices (MDD). Cortrium C3+ Holter is subject to the procedure set out in Annex II of the Council Directive 93/42/EEC.

EC certificate ID (CE-mark): G1 098327 0004

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

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

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

**Louise Flintegaard Ehlert**  
Copenhagen, 2023-02-04

This declaration is valid until 18.03.2023.

**Signatures:**

<b>Controlled Document Approved:</b>	I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.
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