TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 München · Deutschland

Cortrium ApS
Erik Husfeldts Vej 7
2630 Taastrup
Denmark

Ihre Zeichen/Nachricht	Unsere Zeichen/Name	Tel.-Durchwahl/E-Mail	Fax-Durchwahl	Datum	Seite
	FAQ_2023-096	+44 (0) 7706 358210 Veselin.Draganov@tuvsud.com	-	15 Mar. 2023	1 von 3

Confirmation according to Regulation (EU) 2017/745 (MDR), Article 97

Legal Manufacturer: Cortrium ApS

Dear Sir or Madam,

Please find enclosed the information on the status of the conformity assessment procedure for the above-mentioned manufacturer according to Regulation (EU) 2017/745 (MDR), Art.97 in conjunction with MDCG 2022-18, Dec.2022.

1. STATUS - CONFORMITY ASSESSMENT PROCEDURE

TÜV SÜD Product Service GmbH confirms that the application for MDR certification has been accepted and the contract with the manufacturer has been signed (according to MDR Annex VII 4.3), including the expected timeline of conformity assessment procedure (CAP) as follows:

CAP	***Detail Information***	***Status***	***Date***
Application for MDR certification	Annex IX excluding chapter II. Scope of application/products requested see attachment*	accepted	08.02.2023
Contract with the manufacturer	Framework Agreement	signed	21.12.2022
MDR Stage 1 Audit	#75957876	conducted	10.02.2023
Assessment of Technical Documentation	Technical Documentation for Basic UDI-DI 5745000379HolterMonitorVN	ongoing	Mar.2023

	5745000379033HolterMoni-torVN submitted by manufacturer at 06.01.2023		
MDR Stage 2 Audit	#75957876	conducted	14.02.203
Certification decision	Issuance of certificate	planned	Apr.2023

To the present status of assessment, no major safety related shortcomings were identified.

The time dependency is conditioned by the type and extent of potential non-conformities, the submission of evidence on the part of the manufacturer and the availability of the corresponding qualified personnel. For this, further months must be expected for the evaluation rounds before a final positive or negative certification decision can be pronounced for this application.

Due to the large number of certification requests and complexity of the MDR requirements, it is not possible to carry out the certification activities at an earlier stage.

2. INFORMATION

TÜV SÜD Product Service GmbH is aware of the guideline for the notified body to inform the competent authority about the major safety-related shortcomings identified during the conformity assessment defined within MDCG 2022-18, Dec.2022.
Based on the existing legally binding regulations according to Art. 109, MDR the notified bodies are currently not obliged to follow the intent of MDCG 2022-18, Dec.2022 as there is no legal basis for such an interpretation.

Sincerely

TÜV SÜD Product Service GmbH
Medical and Health Services

Signatur: Veselin Draganov
Veselin Draganov (15. März 2023 19:24 GMT)

E-Mail: Veselin.Draganov@tuvsud.com

Veselin Draganov
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Signatur: Hoyer Julia
Hoyer Julia (16. März 2023 19:29 GMT+1)

E-Mail: Julia.Hoyer@tuvsud.com

Julia Hoyer
Head of Certification Body / Deputy

Product Service

ATTACHMENT

* Scope of application/products requested

Product name	***Article number***	***Basic UDI-DI***	***MDN/MDA Code***	***Intended Purpose***
Cortrium C3+ Holter Monitor (Hardware)	50002	5745000379HolterMonitorVN	MDA 0203	The C3+ is an ambulatory three-channel ECG recorder, intended for recording up to 7 days
Cortrium C3+ Holter Monitor (Software: Apex and CAS)	50002	5745000379033HolterMonitorVN	MDA0315	Cortrium Apex is a transfer and storage software needed for setting up and preparing the C3+. It is intended for in clinics, and hospitals as well as to be used remotely AS is an analysis service intended to be used by Cortriums trained personnel in order to generate reports based on algorithmic calculations a