



EU Quality Management System Certificate

Certificate no.
6703GB448250331

Final Assessment Report no.
6703AU16F

Effective date
2025-03-31

Expiry date
2026-01-15

This is to certify that the quality system of

Corscience GmbH & Co. KG

Corscience GmbH & Co. KG, Hartmannstraße 65, 91052 Erlangen, Germany

SRN: DE-MF-000007889

For design, production, and final product inspection/testing of
Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapters I and III of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2025-03-31

For the issuing office
**DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany**



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com


Annika Chiil
Certification Body



DNV

Certificate no.: 6703GB448250331
Place and date: Hamburg, 2025-03-31

Preceding certificate

Certificate no.	Issue date	Identification of changes
6703GB448241119	2024-11-19	Typo Correction
6703GB448241120	2024-11-20	Addition of MDA 0305 (IIb)

Sites covered by this certificate

Corscience GmbH & Co. KG, Hartmannstraße 65, 91052 Erlangen, Germany





DNV

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Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0203	Z120503	ELECTROCARDIOGRAPHS

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0305	C020401	EXTERNAL CARDIOVERSION DEFIBRILLATOR ELECTRODE PADS

Intended purpose

MCS2-Hardpads have no medical purpose of their own and are only used in combination with MEDUCORE Standard2 and MCS2-Connect.

MCS2-Hardpads support the treatment of cardiac arrests and arrhythmias with defibrillation and cardioversion therapy by transmitting energy to the patient for defibrillation or cardioversion

Category	EMDN code	Medical devices/groups of medical devices
MDA 0203	Z120302	VITAL SIGNS MONITORING INSTRUMENTS

Intended purpose

The MCS2-SoftTip, MCS2-Wrap and MCS2-Earclip reusable pulse oximetry sensors are only used in combination with MEDUCORE Standard² and MCS2-Adapt. The reusable pulse oximetry sensors MCS2-SoftTip, MCS2-Wrap and MCS2-Earclip support the examination of patients by measuring oxygen saturation and pulse rate.

The MCS2-Wrap disposable pulse oximetry sensors are only used in combination with MEDUCORE Standard² and MCS2-Adapt. The disposable pulse oximetry sensors MCS2-Wrap support the examination of patients by measuring oxygen saturation and pulse rate.

