



EU-Quality Management Certificate



This is to certify that the company

Fleischhacker GmbH & Co. KG Laboreinrichtungen Medizintechnik

An der Silberkuhle 18
58239 Schwerte
Germany

has implemented a complete Quality Management System for each phase from Design to Final Testing of the products.

Through an audit, documented in a report, carried out by DQS Medizinprodukte GmbH, the proof was provided that this quality management system meets the requirements according to

Annex IX of the Regulation (EU) 2017/745 **CONFORMITY ASSESSMENT PROCEDURE ON THE BASIS OF A QUALITY MANAGEMENT SYSTEM** **AND AN ASSESSMENT OF THE TECHNICAL DOCUMENTATION**

regarding the medical devices listed in the Annex:

The manufacturer shall be subject to surveillance in accordance with Annex IX, Chapter 1, Section 3.

The CE marking with the identification number of the Notified Body (0297) may be affixed on the devices listed on the certificate.

In case of devices placed on the market in sterile condition, devices with a measuring function or for devices which are reusable surgical instruments, the involvement of the Notified Body in these procedures shall be limited: in case of products that are placed on the market in sterile condition, limited to the aspects of manufacture concerned with securing and maintaining sterile condition; in the case of devices with a measuring function limited to the aspects related to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments limited to the aspects related to reuse, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, as well as the related instructions for use.

Certificate registration no.	DE-MF-000006961
Certificate ID	170775726
Previous certificate-ID	n/a
Effective date	2021-11-04
Expiry date	2026-11-03
Frankfurt am Main,	2021-11-04



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlf.de
BS-MDR-094

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.



Annex to EU Quality Management Certificate
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Fleischhacker GmbH & Co. KG
Laboreinrichtungen Medizintechnik

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Product name	Risk class	Intended Use
MediConnect 3	Ila	MediConnect is intended to provide DICOM workstation functionality for making diagnosis based on echocardiographic or radiological images and examination results such as Echo, CT scans, X-Ray pictures and ECG signals. In particular MediConnect provides the means to measure distances and volumes in images and time periods in ECG signals (Image processing).

Examinations and tests performed (e.g. Reference to relevant CS, harmonised standards, test reports and audit report):
530379_A208204MEDAuditbericht_MDRStufell2021-09-02 dated 2021-10-03

Reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered:
n/a