EU Quality Management System Certificate

We hereby certify the company

Andreas Hettich GmbH
Föhrenstraße 12
78532 Tuttlingen
Germany

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2024-12-20	Registration No.	D1459300007
Valid until	2027-08-25	Report No.	P24-00121-319701

Stuttgart, 2024-12-20

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Centrifuges for separation of blood components for transfusion purposes and for preparatory diagnostics of transfusion blood

Risk class: IIa

The certificate is based on the previous certificate

D1459300004 (2022-10-25)

with the following changes to D1459300004:
Change of company name from "Andreas Hettich GmbH & Co. KG" to "Andreas Hettich GmbH"