DECLARATION OF CONFORMITY

DEHAS Medizintechnik GmbH
Wesloer Strasse 112, Gebäude M
23568 Lübeck,
GERMANY

CE

Quality Mix HF; Quality Mix LF and accessories **0482**

Classification: IIb

Classification criteria: Clause 3.2, Rule 11 of Annex IX of the MDD

We hereby declare with sole responsibility that the above products comply with the following guidelines and standards of the EC Council. All supporting documents are kept on the premises of the manufacturer and the notified authority.

Directives: General Application Directives: Medical Device Directive (MDD), Council Directive 93/42/EEC of 14 June 1993 Annex II, 3 on medical devices of the European Parliament.

Applied standards:

EN 980:2008
EN 1041:2008
EN ISO 14971:2013
ISO 15001:2011
ISO 15002:2008
ISO 15223-1:2012
ISO 11195:2018
ISO 18562-1:2017
ISO 18562-2:2017
ISO 18562-3:2017

Notified authority:	Medcert GmbH / CE 0482
Address:	Pilatuspool 2, 20355 Hamburg, GERMANY
Certificate number:	4153DE410180612 Expiration date: 11/2021
Devices already manufactured:	Traceable by serial number
Valid from/to:	06/2018 to expiration date
Manufacturer representative:	Quality manager
Position:	Quality systems
Date of issue:	06/2018