

EU Declaration of Conformity



For the Class IIb medical device

modula

Basic UDI-DI: 426017976ROUL9

with serial numbers from 24 MODULA 0001 to 24 MODULA 9999,

we,

DWA GmbH & Co. KG
Großer Sand 8
76698 Ubstadt-Weiher
Germany
(SRN: DE-MF-000008370)

, declare in our function as manufacturer and under our sole responsibility conformity with the requirements of the following regulation:

REGULATION (EU) 2017/745

of the European parliament and of the council of 5 April 2017 on medical devices, amending directive 2001/83/EC, regulation (EC) No 178/2002 and regulation (EC) No 1223/2009 and repealing council directives 90/385/EEC and 93/42/EEC.

Conformity of the named product with the General Safety and Performance Requirements of Annex I of the regulation is demonstrated in technical documentation, with conformity assessment procedure according to Annex IX Chapter I, III and Section 4.

The product complies with provisions of Directive 2011/65/EU and Commission delegated Directive (EU) 2015/863, and the provisions about information communication according to Regulation (EC) No. 1907/2006.

Conformity is met with directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

Essential health and safety requirements according to Directive 2006/42/EC are met.

All applicable harmonized standards are met.

Notified Body Identification No. 0044
TÜV NORD CERT GmbH
Am TÜV 1
45307 Essen
Germany

Certificate Reg.- No.: 44 911 150580

DWA GmbH & Co. KG
Großer Sand 8
76698 Ubstadt-Weiher
Tel.: 07251-89000

Ubstadt-Weiher, 2024-01-10


D. Hendrik Kheusels, General
Manager