

EC Declaration of Conformity

For the Class IIb medical device

HemoRO 4 ONE

a Single-User Reverse Osmosis System

with serial numbers from 22 HRO41 0100 to 22 HRO41 9999,

we,

DWA GmbH & Co. KG
Großer Sand 8
76698 Ubstadt-Weiher
Germany,

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

93/42/EEC

Council directive issued 14 June 1993 concerning medical devices
last amended by directive 2007/47/EC.

Conformity of the named product with the Essential Requirements of Annex I of the directive is demonstrated in technical documentation.

All applicable harmonized standards are met.

Reg.-No. 44 232 150580

Notified Body EC reference no. 0044
TÜV NORD CERT GmbH
Langemarckstraße 20
45141 Essen
Germany

Ubstadt-Weiher, 2022-06-03



B. Gegenhuber, General Manager