

EU Declaration of conformity

Class IIb medical product

valid until: 31.12.2028

Intermedt Medizin & Technik GmbH
Gewerbestraße-Süd 13
26842 Ostrhauderfehn
Germany
SRN (EUDAMED): DE-MF-000006369

We hereby declare in our sole responsibility that the

Dialysis concentrate production system
ECOMix (Basic UDI-DI 426077082ECOMixD7) consisting of:
ECOMix Revolution (Art. No. IM3284, UDI-DI 4260770820024),
ECOCart

complies with all the applicable requirements of the (EU)2017/745 Art. 120(3).

Compliance of the designated products with the fundamental requirements of the directive is demonstrated by the technical documentation and its full conformance with the standards specified. Compliance with the requirements of Appendix II of the Directive 93/42/EEC is demonstrated by the following certificates:

Certificate from 15.02.2019, Reg.-No. 44 232 130544, certifying compliance with Appendix II of the directive 93/42/EEC on medical products of 05.09.2007; valid until: 20.02.2024 (Report No.: 3523 4287; Notified body: TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany, ID number: 0044)

DIMDI Code: DE/00 000 43487, Form number: 00227304

Certificate of the quality management system referred to DIN EN ISO 13485:2016 of 17.02.2022, valid until: 20.02.2025 (Reg.-No.: 44 221 130544; Report No.: 3531 3710)

We also declare that these products comply with all the applicable requirements of the Directive 2011/65/EU as well as with the Directive 2015/863/EU for the change of appendix II of the Directive 2011/65/EU (RoHS 3).

Melsungen, 15.02.2024

Place, Date

Melanie Bubenik, Managing Director

Ostrhauderfehn, 15.02.2024

Place, Date

Markus Lorek, PRRC

List of ECOCarts (with Art. No. & UDI-DI):

ECOCart DSK-0252-GW-585-45 (IM3773, 4260770820000), **ECOCart** DSK-0252-GW-622-45-Rev (IM3724, 4260770820031), **ECOCart** DSK-0252-GW-622-45-ToGo (IM3725, 4260770820048), **ECOCart** DSK-0252-GW-750-35 (IM3774, 4260770820055), **ECOCart** DSK-0252-GW-800-35-Rev (IM3681, 4260770820062), **ECOCart** DSK-0252-GW-800-35-ToGo (IM3682, 4260770820079), **ECOCart** DSK-0262-GW-585-45 (IM3776, 4260770820086), **ECOCart** DSK-0262-GW-622-45-Rev (IM3728, 4260770820093), **ECOCart** DSK-0262-GW-622-45-ToGo (IM3729, 4260770820109), **ECOCart** DSK-0262-GW-750-35 (IM3775, 4260770820116), **ECOCart** DSK-0262-GW-800-35-Rev (IM3685, 4260770820123), **ECOCart** DSK-0262-GW-800-35-ToGo (IM3686, 4260770820130), **ECOCart** DSK-0442-GW-B8-585-45 (IM3949, 4260770820147), **ECOCart** DSK-0452-GW-622-45-Rev (IM3461, 4260770820154), **ECOCart** DSK-0452-GW-B9-585-45 (IM3803, 4260770820161), **ECOCart** DSK-0452-GW-B9-622-45-Rev (IM3734, 4260770820178), **ECOCart** DSK-0452-GW-B9-622-45-ToGo (IM3733, 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(IM3753, 4260770820680), **ECOCart** DSK-0662-GW-750-35 (IM3790, 4260770820697), **ECOCart** DSK-0662-GW-800-35-Rev (IM3709, 4260770820703), **ECOCart** DSK-0662-GW-800-35-ToGo (IM3710, 4260770820710), **ECOCart** DSK-0663-G15W-500-45 (IM3105, 4260770820727), **ECOCart** DSK-0672-GW-585-45 (IM3784, 4260770820734), **ECOCart** DSK-0672-GW-622-45-Rev (IM3754, 4260770820741), **ECOCart** DSK-0672-GW-622-45-ToGo (IM3755, 4260770820758), **ECOCart** DSK-0672-GW-750-35 (IM3787, 4260770820765), **ECOCart** DSK-0672-GW-800-35-Rev (IM3711, 4260770820772), **ECOCart** DSK-0672-GW-800-35-ToGo (IM3712, 4260770820789), **ECOCart** DSK-0673-GW-585-45 (IM3785, 4260770820796), **ECOCart** DSK-0673-GW-622-45-Rev (IM3756, 4260770820802), **ECOCart** DSK-0673-GW-622-45-ToGo (IM3757, 4260770820819), **ECOCart** DSK-0673-GW-750-35 (IM3788, 4260770820826), **ECOCart** DSK-0673-GW-800-35-Rev (IM3713, 4260770820833), **ECOCart** DSK-0673-GW-800-35-ToGo (IM3714, 4260770820840), **ECOCart** DSK-0852-GW-585-45 (IM3793, 4260770820857), **ECOCart** DSK-0852-GW-622-45-Rev (IM3758, 4260770820864), **ECOCart** DSK-0852-GW-622-45-ToGo (IM3759, 4260770820871), **ECOCart** DSK-0852-GW-750-35 (IM3795, 4260770820888), **ECOCart** DSK-0852-GW-800-35-Rev (IM3715, 4260770820895), **ECOCart** DSK-0852-GW-800-35-ToGo (IM3716, 4260770820901), **ECOCart** DSK-0853-GW-585-45 (IM2215, 4260770820918), **ECOCart**

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