

**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)

DMIDS Code: DE/0000043487, Form number: 00415632

Certificate of the quality management system referred to DIN EN ISO 13485:2021 of 12.02.2024, valid until: 20.02.2025 (Reg.-No.: 44 221 130544; Report No.: 3536 2468)

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).

Morschen, 02.05.2024

Place, Date

\_\_\_\_\_  
Melanie Bubenik, Managing Director

Ostrhauderfehn, 02.05.2024

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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