
Declaration of conformity (EC)

class IIb medical product:

valid until: 20.02.2022

Intermedt Medizin & Technik GmbH
Gewerbestraße-Süd 13
26842 Ostrhauderfehn
Germany

We hereby declare in our sole responsibility that the

Dialysis concentrate production system:
ECOMix (Art. No. IM2777), **ECOMix Revolution** (Art. No. IM3284), **ECOCart**

complies with all the applicable requirements of the Directive 93/42/EEC (last revised by Directive 2007/47/EC).

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 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

Report No.: 3523 4287
Valid until: 20.02.2024
Notified body: TÜV Nord Cert GmbH
Langemarckstr. 20
45141 Essen
Germany
ID number: 0044

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

Plus:

Certificate of the quality management system referred to DIN EN ISO 13485:2016 of 15.02.2019, valid until: 20.02.2022

Reg.-No.: 44 221 130544
Report No.: 3523 4286

We also declare that these products comply with all the applicable requirements of the Directive 2011/65/EU (RoHS 2). Compliance is demonstrated by the technical documentation.

Ostrhauderfehn, 03.04.2019

Place, date



Christoph Dumschat/Managing Director

List of ECOCards (Art. No. in brackets):

ECOCart DSK-0252-GW-585-45 (IM3773), **ECOCart** DSK-0252-GW-622-45-Rev (IM3724), **ECOCart** DSK-0252-GW-622-45-ToGo (IM3725), **ECOCart** DSK-0252-GW-750-35 (IM3774), **ECOCart** DSK-0252-GW-800-35-Rev (IM3681), **ECOCart** DSK-0252-GW-800-35-ToGo (IM3682), **ECOCart** DSK-0262-GW-585-45 (IM3776), **ECOCart** DSK-0262-GW-622-45-Rev (IM3728), **ECOCart** DSK-0262-GW-622-45-ToGo (IM3729), **ECOCart** DSK-0262-GW-750-35 (IM3775), **ECOCart** DSK-0262-GW-800-35-Rev (IM3685), **ECOCart** DSK-0262-GW-800-35-ToGo (IM3686), **ECOCart** DSK-0442-GW-B8-585-45 (IM3949), **ECOCart** DSK-0452-GW-622-45 (IM3461), **ECOCart** DSK-0452-GW-B9-585-45 (IM3803), **ECOCart** DSK-0452-GW-B9-622-45-Rev (IM3734), **ECOCart** DSK-0452-GW-B9-622-45-ToGo (IM3733), **ECOCart** DSK-0452-GW-B9-750-35 (IM3802), **ECOCart** DSK-0452-GW-B9-800-35-Rev (IM3690), **ECOCart** DSK-0452-GW-B9-800-35-ToGo (IM3691), **ECOCart** DSK-0453-GW-585-45 (IM1966), **ECOCart** DSK-0453-GW-622-45-Rev (IM3735), **ECOCart** DSK-0453-GW-622-45-ToGo (IM3736), **ECOCart** DSK-0453-GW-750-35 (IM2211), **ECOCart** DSK-0453-GW-800-35-Rev (IM3598), **ECOCart** DSK-0453-GW-800-35-ToGo (IM3693), **ECOCart** DSK-0453-GW-Cit-B9-622-45 (IM3898), **ECOCart** DSK-0462-GW-585-45 (IM3287), **ECOCart** DSK-0462-GW-622-45-Rev (IM3738), **ECOCart** DSK-0462-GW-622-45-ToGo (IM3739), **ECOCart** DSK-0462-GW-750-35 (IM3777), **ECOCart** DSK-0462-GW-800-35-Rev (IM3695), **ECOCart** DSK-0462-GW-800-35-ToGo (IM3696), **ECOCart** DSK-0463-GW-585-45 (IM3781), **ECOCart** DSK-0463-GW-622-45-Rev (IM3740), **ECOCart** DSK-0463-GW-622-45-ToGo (IM3741), **ECOCart** DSK-0463-GW-750-35 (IM3778), **ECOCart** DSK-0463-GW-800-35-Rev (IM3692), **ECOCart** DSK-0463-GW-800-35-ToGo (IM3694), **ECOCart** DSK-0472-GW-585-45 (IM3782), **ECOCart** DSK-0472-GW-622-45-Rev (IM3742), **ECOCart** DSK-0472-GW-622-45-ToGo (IM3743), **ECOCart** DSK-0472-GW-750-35 (IM3779), **ECOCart** DSK-0472-GW-800-35-Rev (IM3442), **ECOCart** DSK-0472-GW-800-35-ToGo (IM3699), **ECOCart** DSK-0473-GW-585-45 (IM3783), **ECOCart** DSK-0473-GW-622-45-Rev (IM3744), **ECOCart** DSK-0473-GW-622-45-ToGo (IM3745), **ECOCart** DSK-0473-GW-750-35 (IM3780), **ECOCart** DSK-0473-GW-800-35-Rev (IM3700), **ECOCart** DSK-0473-GW-800-35-ToGo (IM3701), **ECOCart** DSK-0652-GW-622-45-Rev (IM3460), **ECOCart** DSK-0652-GW-B9-585-45 (IM3792), **ECOCart** DSK-0652-GW-B9-622-45-Rev (IM3867), **ECOCart** DSK-0652-GW-B9-622-45-ToGo (IM3747), **ECOCart** DSK-0652-GW-B9-750-35 (IM3791), **ECOCart** DSK-0652-GW-B9-800-35-Rev (IM3703), **ECOCart** DSK-0652-GW-B9-800-35-ToGo (IM3704), **ECOCart** DSK-0653-GW-585-45 (IM1970), **ECOCart** DSK-0653-GW-622-45-Rev (IM3938), **ECOCart** DSK-0653-GW-750-35 (IM2213), **ECOCart** DSK-0653-GW-800-35-Rev (IM3597), **ECOCart** DSK-0653-GW-Cit-B9-622-45-Rev (IM5007), **ECOCart** DSK-0653-GW-Cit-B9-622-45-ToGo (IM3899), **ECOCart** DSK-0662-GW-585-45 (IM3288), **ECOCart** DSK-0662-GW-622-45-Rev (IM3752), **ECOCart** DSK-0662-GW-622-45-ToGo (IM3753), **ECOCart** DSK-0662-GW-750-35 (IM3790), **ECOCart** DSK-0662-GW-800-35-Rev (IM3709), **ECOCart** DSK-0662-GW-800-35-ToGo (IM3710), **ECOCart** DSK-0663-G15W-500-45 (IM3105), **ECOCart** DSK-0672-GW-585-45 (IM3784), **ECOCart** DSK-0672-GW-622-45-Rev (IM3754), **ECOCart** DSK-0672-GW-622-45-ToGo (IM3755), **ECOCart** DSK-0672-GW-750-35 (IM3787), **ECOCart** DSK-0672-GW-800-35-Rev (IM3711), **ECOCart** DSK-0672-GW-800-35-ToGo (IM3712), **ECOCart** DSK-0673-GW-585-45 (IM3785), **ECOCart** DSK-0673-GW-622-45-Rev (IM3756), **ECOCart** DSK-0673-GW-622-45-ToGo (IM3757), **ECOCart** DSK-0673-GW-750-35 (IM3788), **ECOCart** DSK-0673-GW-800-35-Rev (IM3713), **ECOCart** DSK-0673-GW-800-35-ToGo (IM3714), **ECOCart** DSK-0852-GW-585-45 (IM3793), **ECOCart** DSK-0852-GW-622-45-Rev (IM3758), **ECOCart** DSK-0852-GW-622-45-ToGo (IM3759), **ECOCart** DSK-0852-GW-750-35 (IM3795), **ECOCart** DSK-0852-GW-800-35-Rev (IM3715), **ECOCart** DSK-0852-GW-800-35-ToGo (IM3716), **ECOCart** DSK-0853-GW-585-45 (IM2215), **ECOCart** DSK-0853-GW-622-45-Rev (IM3939), **ECOCart** DSK-0862-GW-585-45 (IM3794), **ECOCart** DSK-0862-GW-622-45-Rev (IM3760),

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35-ToGo (IM4035), **ECOCart** DSK-36A3-GW-750-35 (IM2276), **ECOCart** DSK-36C2-GW-750-35 (IM2838), **ECOCart** DSK-36M2-GW-622-45-Rev (IM4058), **ECOCart** DSK-36C2-GW-Cit-585-45 (IM3261), **ECOCart** DSK-36C2-GW-Cit-750-35 (IM5004), **ECOCart** DSK-36K3-GW-750-35 (IM2355), **ECOCart** DSK-36K4-GW-750-35 (IM2985), **ECOCart** DSK-36L2-GW-750-35 (IM1799), **ECOCart** DSK-3752-GW-585-45 (IM3242), **ECOCart** DSK-3752-GW-750-35 (IM2354), **ECOCart** DSK-37A4-GW-750-35 (IM2830), **ECOCart** DSK-37S3-GW-750-35 (IM1496), **ECOCart** DSK-37S4-GW-750-35 (IM1542), **ECOCart** DSK-3852-G15W-650-35 (IM3292), **ECOCart** DSK-3852-G2W-600-35-Rev (IM3642), **ECOCart** DSK-3852-GW-585-45 (IM2868), **ECOCart** DSK-3852-GW-622-45-Rev (IM3962), **ECOCart** DSK-3852-GW-622-45-ToGo (IM3963), **ECOCart** DSK-3852-GW-750-35 (IM2168), **ECOCart** DSK-3852-GW-800-35-Rev (IM3596), **ECOCart** DSK-3852-GW-800-35-ToGo (IM3961), **ECOCart** DSK-3853-G2W-600-35-Rev (IM3850), **ECOCart** DSK-3853-GW-2-750-35 (IM1996), **ECOCart** DSK-3853-GW-622-45-Rev (IM3995), **ECOCart** DSK-3853-GW-622-45-ToGo (IM4036), **ECOCart** DSK-3853-GW-750-35 (IM2037), **ECOCart** DSK-3853-GW-800-35-Rev (IM3865), **ECOCart** DSK-3853-GW-800-35-ToGo (IM4037), **ECOCart** DSK-3854-GW-575-45 (IM2372), **ECOCart** DSK-3854-GW-750-35 (IM2719), **ECOCart** DSK-385V-GW-750-35 (IM2294), **ECOCart** DSK-3862-GW-3,5-750-35 (IM1577), **ECOCart** DSK-3862-GW-585-45 (IM2351), **ECOCart** DSK-3862-GW-622-45-Rev (IM3937), **ECOCart** DSK-3862-GW-622-45-ToGo (IM3964), **ECOCart** DSK-3862-GW-750-35 (IM1562), **ECOCart** DSK-3862-GW-800-35-ToGo (IM3965), **ECOCart** DSK-3862-GW-800-35-ToGo (IM3966), **ECOCart** DSK-3862-GW-Cit-585-45 (IM3811), **ECOCart** DSK-3862-GW-Cit-622-45-Rev (IM3826), **ECOCart** DSK-3862-GW-Cit-622-45-ToGo (IM3825), **ECOCart** DSK-3862-GW-Cit-750-35 (IM3807), **ECOCart** DSK-3862-GW-Cit-800-35-Rev (IM3818), **ECOCart** DSK-3862-GW-Cit-800-35-ToGo (IM3819), **ECOCart** DSK-3863-GW-585-45 (IM4052), **ECOCart** DSK-3863-GW-622-45-Rev (IM4038), **ECOCart** DSK-3863-GW-622-45-ToGo (IM4039), **ECOCart** DSK-3863-GW-750-35 (IM1792), **ECOCart** DSK-3863-GW-800-35-Rev (IM4040), **ECOCart** DSK-3863-GW-800-35-ToGo (IM4041), **ECOCart** DSK-3863-GW-Cit-750-35 (IM3874), **ECOCart** DSK-3864-GW-575-45 (IM2372), **ECOCart** DSK-3864-GW-750-35 (IM3386), **ECOCart** DSK-3872-GW-3,5-750-35 (IM1576), **ECOCart** DSK-3872-GW-585-45-Rev (IM3967), **ECOCart** DSK-3872-GW-622-45-Rev (IM3968), **ECOCart** DSK-3872-GW-622-45-ToGo (IM3969), **ECOCart** DSK-3872-GW-750-35 (IM1633), **ECOCart** DSK-3872-GW-800-35-Rev (IM3970), **ECOCart** DSK-3872-GW-800-35-ToGo (IM3971), **ECOCart** DSK-3873-GW-585-45 (IM4053), **ECOCart** DSK-3873-GW-622-45-Rev (IM4042), **ECOCart** DSK-3873-GW-622-45-ToGo (IM4043), **ECOCart** DSK-3873-GW-800-35-Rev (IM4044), **ECOCart** DSK-3873-GW-800-35-ToGo (IM4045), **ECOCart** DSK-38A4-GW-750-35 (IM3108), **ECOCart** DSK-38C2-GW-750-35 (IM3876), **ECOCart** DSK-38L2-GW-750-35 (IM1603), **ECOCart** DSK-5264-GW-2,5-575-45 (IM1815), **ECOCart** DSK-5454-GW-2,5-575-45 (IM2961), **ECOCart** DSK-5462-GW-2-750-35 (IM3438), **ECOCart** DSK-5463-GW-750-35 (IM2466), **ECOCart** DSK-5564-GW-2,5-575-45 (IM1816), **ECOCart** DSK-5654-GW-2,5-575-45 (IM2963), **ECOCart** DSK-5663-G2W-575-35 (IM2713), **ECOCart** DSK-5663-GW-750-35 (IM2465), **ECOCart** DSK-5664-G2W-575-35 (IM3387), **ECOCart** DSK-5764-GW-2,5-575-45 (IM1814), **ECOCart** DSK-5854-GW-2,5-575-45 (IM3856), **ECOCart** DSK-5856-GW-2,5-575-45 (IM2964), **ECOCart** DSK-5862-GW-750-35 (IM3246), **ECOCart** DSK-5864-GW-2,5-575-45 (IM2030), **ECOCart** DSK-5866-GW-2,5-575-45 (IM2004), **ECOCart** DSK-74V4-4-800-35 (IM3443), **ECOCart** DSK-V4V2-4-800-35-Rev (IM3440)