

EC-Declaration of Conformity on Medical Devices

According to annex II of Medical Device Directive 93/42/EEC (2007/47/EG)

Manufacturer: **RECK-Technik GmbH & Co. KG** Engineering Division Sector
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Name of Product: **MOTOmed loop edition 260.xxx**
Basic UDI-DI: 4260193710027P

	REF	SN
Product variants:	MOTOmed loop.l	260.010 xxx-LP-010xxx
	MOTOmed loop.a	260.020 xxx-LP-020xxx
	MOTOmed loop.la	260.030 xxx-LP-030xxx
	MOTOmed loop.la prof	260.039 xxx-LP-039xxx
	MOTOmed loop p.l	260.040 xxx-LP-040xxx
	MOTOmed loop p.la	260.060 xxx-LP-060xxx
	MOTOmed loop light.l	260.100 xxx-LP-100xxx
	MOTOmed loop light.a	260.110 xxx-LP-110xxx
	MOTOmed loop light.la	260.120 xxx-LP-120xxx
	MOTOmed loop kidz.l	260.070 xxx-LP-070xxx
	MOTOmed loop kidz.a	260.080 xxx-LP-080xxx
	MOTOmed loop kidz.la	260.090 xxx-LP-090xxx

Product classification: IIa (rule 9, Medical Device Directive 93/42/EEC)

We hereby declare under our sole responsibility that the above products comply with the relevant provisions of the Medical Devices Directive 93/42/EEC (2007), Annex II, Section 3 and that we are solely responsible for issuing this declaration of conformity.

This Declaration of Conformity is valid until 02.08.2023 (registration no. of certificate: 50293-16-05) or until a revised declaration is made due to product modifications.

Following party was involved in the evaluation of the conformity:
DEKRA Certification GmbH, Handwerkstrasse 15, 70565 Stuttgart, GERMANY
Notified Body No. 0124



Betzenweiler, 24.06.2020

Andreas Reck Executive Director