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
Reckstraße 1–5, 88422 Betzenweiler, GERMANY
phone +49 7374 18-85, fax +49 7374 18-480
email: vigilance@motomed.com

Name of Product:

	REF	SN
Basic UDI-DI: 4260193710017M		
MOTOmed viva2	200.003	xxx-VM2-003xxx
MOTOmed viva2 stativ	200.012	xxx-VM2-012xxx
MOTOmed viva2 light	200.004	xxx-VM2-004xxx
MOTOmed viva2 light stativ	200.021	xxx-VM2-021xxx
MOTOmed viva2 Parkinson	200.008	xxx-VM2-008xxx
Basic UDI-DI: 4260193710047T	REF	SN
MOTOmed letto2	279.003	xxx-LET2-003xxx
MOTOmed letto2	279.024	xxx-LET2-024xxx
MOTOmed letto2	279.008	xxx-LET2-008xxx
MOTOmed letto2	279.016	xxx-LET2-016xxx
Basic UDI-DI: 4260193710067X	REF	SN
MOTOmed gracile12	594.003	xxx-KIG12-003xxx
MOTOmed gracile12 ATAP	594.003 + 599.000	xxx-KIG12-003xxx

Product options: all (according to current pricelist)

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 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, 03.08.2018 **Andreas Reck** Executive Director