RECK
Medical Devices

RECK-Technik GmbH & Co. KG
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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	RECK-Technik GmbH & Co. KG
Manufacturer address and contact details	Reckstraße 1-5 88422 Betzenweiler GERMANY ra@motomed.com
Single Registration Number (SRN)	DE-MF-000005730

Notified body name	DEKRA Certification GmbH Handwerkstraße 15 70565 Stuttgart GERMANY
Notified body number	0124
Directive Certificate number to which this confirmation is made	50293-16-05
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2023-08-02
End date of extended validity/transition period	2028-12-31

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

Directive Certificate as listed above

- Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.
- Expiration after 20 March 2023:
  - Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

Quality Management System (QMS)

- A QMS in accordance with Article 10(9) MDR is in place.

Devices as listed in the attached schedule

- The devices continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

RECK-Technik GmbH & Co. KG

Betzenweiler, 24.07.2023

i. A. Andreas Brauch, PRRC

ra@motomed.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the devices	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR contract was signed	End date of extended validity / transition period
MOTOmed viva2	50293-16-05	2023-08-02	DEKRA Certification GmbH Stuttgart 0124	DEKRA Certification GmbH Stuttgart 0124	2024-05-26
MOTOmed viva2	50293-16-05	2023-08-02	DEKRA Certification GmbH Stuttgart 0124	DEKRA Certification GmbH Stuttgart 0124	2024-05-26
MOTOmed viva2 light	50293-16-05	2023-08-02	DEKRA Certification GmbH Stuttgart 0124	DEKRA Certification GmbH Stuttgart 0124	2024-05-26
MOTOmed viva2 Parkinson	50293-16-05	2023-08-02	DEKRA Certification GmbH Stuttgart 0124	DEKRA Certification GmbH Stuttgart 0124	2024-05-26
MOTOmed letto2	50293-16-05	2023-08-02	DEKRA Certification GmbH Stuttgart 0124	DEKRA Certification GmbH Stuttgart 0124	2024-05-26
MOTOmed gracile12	50293-16-05	2023-08-02	DEKRA Certification GmbH Stuttgart 0124	DEKRA Certification GmbH Stuttgart 0124	2028-12-31
MOTOmed muvi	50293-16-05	2023-08-02	DEKRA Certification GmbH Stuttgart 0124	DEKRA Certification GmbH Stuttgart 0124	2028-12-31
MOTOmed loop	50293-16-05	2023-08-02	DEKRA Certification GmbH Stuttgart 0124	DEKRA Certification GmbH Stuttgart 0124	2028-12-31
MOTOmed layson edition	50293-16-05	2023-08-02	DEKRA Certification GmbH Stuttgart 0124	DEKRA Certification GmbH Stuttgart 0124	2028-12-31