

Manufacturer's Declaration

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

- the validity of certificate issued under Council Directive 93/42/EEC on Medical Devices (MDD) Directive Certificate 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	medica Medizintechnik GmbH
Manufacturer address and contact details	Blumenweg 8 884545 Hochdorf Germany
Single Registration Number (SRN) (if available)	DE-MF-000005058

Notified body name	DQS Medizinprodukte GmbH
Notified body number	0297
Directive Certificate number to which this confirmation is made	Registration no.: 064866 MR2 Unique ID: 170770080
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	02-03-2024
End date of extended validity/transition period	31-12-2028

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:

THERA-Trainer by medica Medizintechnik GmbH

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88454 Hochdorf
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Geschäftsführer
Dr. Jonathan Kopf | Otto Höbel
Rgr. Ulm HRB 640839
WEEE-Reg.-Nr.: DE 10764186
USt.-IdNr. DE144890393

Kreissparkasse Biberach
IBAN DE88 6545 0070 0000 0023 14
SWIFT SBCRDE66

Commerzbank Biberach
IBAN DE20 6544 0087 0130 4567 00
SWIFT COBADEFF654

➤ **Directive Certificate** as listed above

- Directive Certificate covering the listed devices were issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

Expired/expires *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/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Devices as listed in the attached schedule**

- The devices continue to comply with the 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.

Hochdorf, 2024-02-28

medica Medizintechnik GmbH

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Otto Höbel
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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 application was lodged/contract signed	End date of extended validity / transition period	Substitute Device (if applicable)
Omnicycle						Omnicycle connect
THERA-Trainer tigo						-
THERA-Trainer veho						-
THERA-vital	Registration no.: 064866 MR2		DQS Medizinprodukte GmbH	DQS Medizinprodukte GmbH	31.12.2028	-
THERA-live	Unique ID: 170770080	02.03.2024	DQS Medizinprodukte GmbH	DQS Medizinprodukte GmbH		-
THERA-Trainer mobi						-
THERA-Trainer lyra						THERA-Trainer lyra next
THERA-Trainer bemo						-

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