

Declaration of Conformity

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745



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

- the validity of certificates issued under 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	ergoline GmbH Lindenstr. 5 72475 Bitz Germany
SRN of manufacturer	DE-MF-000006402

Notified body name	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Notified body number	0123
Directive Certificate number to which this confirmation is made	G1 044463 0022 Rev. 01
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-05-26

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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

Formal applications to the Notified Body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

The Notified Body confirmed the formal application and written agreement with Confirmation Letter CL 044463 0044 Rev. 00.

Quality Management System

A Notified Body has issued the attached certificate G10 044463 0038 Rev. 00 for the MDR-compliant Quality Management System.

Devices as listed in the attached schedule

- The device(s) continue to comply with MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) 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.

Bitz, 2024-04-24

Andreas Maurer
Name
Director Quality Management / Regulatory Affairs

A handwritten signature in blue ink, appearing to read "A. Maurer", written over a light blue horizontal line.

Signature

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Schedule of Devices

This Declaration is valid for the following devices including accessories and spare parts:

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) 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
ers2 Software	G1 044463 0022 Rev. 01	2024-05-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	December 2028
Bicycle ergometer series with/without vital parameter monitoring covering: ergoselect 4/5, 100, 150, 200 and 600 optibike basic/plus	G1 044463 0022 Rev. 01	2024-05-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	December 2028
Reclining ergometer series with/without vital parameter monitoring covering: ergoselect 10, 12 and 1200	G1 044463 0022 Rev. 01	2024-05-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	December 2028