

DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III

Parameters	Value
Manufacturer name	Clinomic Medical GmbH
Manufacturer address	Forckenbeckstraße 66, 52074 Aachen, GERMANY
Manufacturer SRN (Single Registration Number)	DE-MF-000013339
Product name and Version	MonaOS 3 (v.3.0.0)
Basic UDI-DI	4260735730039D
Classification (MDR)	Class IIa
Device Group	MDA 0315 - Software Z12030201 - CENTRAL INFORMATION COMPUTING SYSTEMS
Rule number according to Annex VIII (MDR)	1 and 11
Notified Body name	TÜV SÜD Product Service GmbH
Notified Body address	Ridlerstraße 65, 80339 München, Germany
Notified Body identification number	0123
EU Certificate (MDR)	EU Quality Management System Certificate Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I No. G15 110050 0004 Rev. 00

We, **Clinomic Medical GmbH**, declare under our sole responsibility that the product specified above meets the provision of the MDR 2017/745.

The above-mentioned product is a medical device according to Article 2 (1) of the MDR 2017/745. It fulfils the applicable general safety and performance requirements according to MDR 2017/745

This Declaration of Conformity is supported by **EU Quality Management System Certificate (MDR) No. G15 110050 0004 Rev. 00**, issued by **TÜV SÜD Product Service GmbH** on **2026-07-14**, valid until **2028-01-25**.

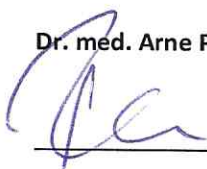
Clinomic Medical GmbH uses this conformity procedure for the CE-labelling of their product according to the MDR 2017/745.

CE 0123

Place and date of issue of the declaration:

Aachen, 2026-07-14

Name and function of the signatory:

Dr. med. Arne Peine, CTO**Prof. Dr. med. Lukas Martin, CEO**