

DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 on Medical Devices, Art. 52(7), Annex I, II 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	Mona Terminal 2
Basic UDI-DI	4260735730029B
Classification (MDR)	Class I
Device Group	Z1203020201 - MULTI-PARAMETER PATIENT BEDSIDE MONITORS
Rule number according to Annex VIII (MDR)	1 and 13
The product covered by this Declaration of Conformity complies with the relevant EU Union legislation	• Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) • Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment (RED) • Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
EU (QMS) Certificate	ISO 13485:2016 (EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021) No. Q5 110050 0001 Rev. 03
Notified Body	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München, Germania ID: 0123
EU RED Certificate*	TPS-RED- 500629 i01 (Radio Equipment Directive 2014/53/EU, Annex III Module B
Harmonized and Non-harmonized standards related to RED	• EN 300 328 V2.2.2 (2019-07) • EN 300 330 V2.1.1 (2017-02) • EN 300 440 V2.2.1 (2018-07) • EN 301 893 V2.1.1 (2017-05) • EN 301 908-1 V13.1.1 (2019-11); EN 301 908-2 V13.1.1 (2020-06); EN 301 908-13 V13.1.1 (2019-11); EN 301 908-15 V15.1.1 (2020-01) • EN 301 489-1 V1.9.2 (2011-09); EN 301 489-1: V2.2.3 (2019-11); EN 301 489-19 V2.1.1 (2019-04); EN 301 489-52:V1.2.1 (2021-11) • EN 303 413 V1.1.1 (2017-06) • EN 305 550 V2.1.0 (2017-10) • EN 55035:2017 • IEC 60601-1-2:2014; IEC 60601-1-2:2014/AMD1:2020 • EN 62311:2008 • EN 62368-1:2014/A11:2017

*The notified body TÜV SÜD Product Service GmbH has carried out an EU type examination for RED 2014/53/EU Article 3.2 and issued the certificate no. TPS-RED- 500629i01 displayed.

We, **Clinomic Medical GmbH**, declare under our sole responsibility that the product specified above meets the provision of the Regulation (EU) 2017/745 (**MDR**), as well as complies with applicable requirements of the Directive 2014/53/EU (**RED**) and Directive 2011/65/EU (**RoHS**).

Conformity has been established by means of the conformity assessment procedure of self-declaration pursuant to MDR 2017/745, Art. 52(7), Annex I, II and III.

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



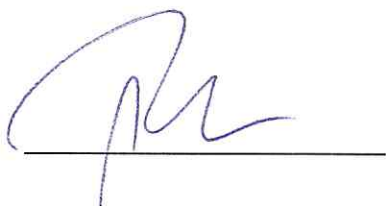
The declaration is valid with the date of the signature.

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. Lukas Martin, CEO

