DECLARATION OF CONFORMITY

MCD Medical Line THA.leia³

2000075M 2000085M	MCD Medical Line THA.leia³

MCD Medical Computers Deutschland GmbH
Konrad-Zuse-Ring 17 A/B
41179 Moenchengladbach
– Germany –

hereby declare in sole responsibility that the above mentioned system(s) comply with the essential requirements of the following EC Directives as well as EN 60601-1-2:2015 A1:2021 , if used for its intended purpose:

For Models w/o WiFi-Module:	(1)	EMC-Directive 2014/30/EU
	(2)	Low Voltage Directive 2014/35/EU
For Models with WiFi-Modul:	(3)	RED-Directive 2014/53/EU

Applied harmonized standards or normative documents:

(1) & (2)	EN 55035:2017/A11:2020; EN 60601-1-2:2015 A1:2021 EN 62368-1:2020 + A11:2020 (in conjunction with the power supply listed below)
(3)	EN 55035:2015 + AC:2016 + A11:2020 + A1:2020

Power supply to be used with the system:

Bicker BEO-1412M	EN 60601-1-2: 2015, EN 55011: 2009+A1:2010 Class B, EN 61000-3-2: 2014, EN 61000-3-3: 2013, EN 60601-1:2006+A1:2013 Certificate No. B 084165 0008, EN 62368-1: 2014/A11:2017 Certificate No. B 084165 0009
Bicker BEO-2512M	EN 60601-1-2:2007, EN 55011:2009+A1:2010 Group I Class B, EN55022:2010 Class B, EN 55024:2010, EN 61000-3-2:2006+A1:2009+A2:2009, EN 61000-3-3:2008, EN 60601-1:2006;A1 Nemko Certificate Nr. P14218306, EN 60950-1:2006+A11+A1+A12 Nemko Certificate No. EL-1211-224590-000
Bicker BET-1612M	EN 60601-1-2:2007+AC:2010, CISPR 11:2009+A1:2010 (Gruppe1) Class B, IEC 61000-3-2:2005+A1:2008+A2:2009 Class D, EC 61000-3-3:2013, EN 60601-1:2006+A11 Certificate No. TA 50296386

This declaration certifies compliance with the guidelines mentioned, but does not include any guarantee of properties. The safety instructions in the supplied product documentation must be observed.

TÜVRheinland ZERTIFIZIERT
Management System EN ISO 13485:2016
www.tuv.com ID 9105055459

EU RoHS / REACH Statement

MCD feels responsible for the environment and the health of user, patients and others as well. Therefore MCD products are designed an manufactured in order to comply with currently valid RoHS directive (2011/65/EC) / (EU 2015/863) and the REACH regulation (1907/2006) mentioned below.

RoHS:

We hereby declare in sole responsibility that the mentioned above products are in full compliance with EU Directive 2011/65/EC and EU 2015/863 with respect to the following substances:

Substance	Element	Limit value (%)
Lead	Pb	0,1
Mercury	Hg	0,1
Cadmium	Cd	0,01
Hexavalent chromium	Cr (VI)	0,1
Polybrominated biphenyls	PBB	0,1
Polybrominated diphenyl ethers	PBDE	0,1
Bis(2-ethylhexyl) phthalate	DEHP	0,1
Butyl benzyl phthalate	BBP	0,1
Dibutyl phthalate	DBP	0,1
Diisobutyl phthalate	DIBP	0,1

REACH:

MCD Medical Computers Deutschland GmbH is a manufacturer of pc systems for medical environments.

We fulfill the REACH Regulation (Regulation (EC) no. 1907/2006) related to the requirements with relevance and continuously monitor changes of the REACH Regulation and the list of candidates.

We will inform you in the context of our business relationship about changes of delivered products caused by the EC REACH Regulation and will, in the individual case, coordinate suitable measures with you. With reference to article 33 of the REACH ordinance we inform you about the following:

An up-to-date list of candidates (updated June 27th, 2024, last check for topicality July 04th, 2024) in accordance with article 59 (1, 10) of the ordinance (EC) no. 1907/2006 (REACH) was published.

The mentioned above products and their packaging do not contain any substances of this current list of candidates in concentrations of more than 0.1 mass %.

Latex:

MCD takes the adverse effects of latex on users, patients and third parties seriously. In the product "MCD Medical Line THA.leia³", as far as the research carried out on the part of MCD shows, no components are installed or used which consist of or partly consist of latex.

Moenchengladbach, 2024-07-05	Thomas Hollex	
(Place and date of the exhibit)	(Issuer)	(Signature)

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