



DECLARATION OF CONFORMITY

MCD Medical Line AESCU.certus²

2000038M	MCD Medical Line AESCU.certus ²
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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, if used for its intended purpose:

EMC Directive 2014/30/EC
 Low Voltage Directive 2014/35/EC

Applied harmonized standards or normative documents:

EN 60601-1-2:2007 Clause 6 | IEC 60601-1-2:2007, Edition 3.0 Clause 6
 EN 55022:2006 + A1:2007 | EN 55011:2007+ A2:2007
 EN 61000-3-2:2006 + A1:2009 + A2:2009 | EN 61000-3-3:2008

Power supply

Bicker
 BEO-1024M
 EN 60601-1-2: 2007 | EN 55011: 2009+A1:2010 Class B | EN 55022:
 2010+AC:2011 Class B | EN 55024: 2010 | EN 61000-6-3: 2007+A1:2011 | EN
 61000-6-1: 2007 | EN 61204-3: 2000 | EN 61000-3-2: 2014 Class D | EN 61000-3-
 3: 2013 | EN 60601-1: 2006+A11+A12 Certificate No. TA 50204096 | EN 60950-1:
 2006+A11+A1+A12+A2 Certificate No. R 50202109

This declaration certifies the compliance with the indicated directives but implies no warranty of characteristics. The safety of the supplied product documentation must be observed.



Management
 System
 EN ISO
 13485:2012
 www.tuv.com
 ID 9105055459



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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 and manufactured in order to comply with currently valid RoHS directive (2011/65/EC) 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 EC Directive 2011/65/EC with respect to the following substances:

Substance	Element	Limit value (%)
Lead	Pb	0,1
Mercury	Hg	0,1
Hexavalent chromium	Cr (VI)	0,1
Polybrominated biphenyls	PBB	0,1
Polybrominated diphenyl ethers	PBDE	0,1
Cadmium	Cd	0,01

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.

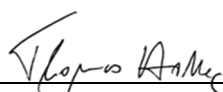
We will inform you in the context of our business relationship about changes of delivered products caused by the EC REACH Regulation and will, in the individual case, coordinate suitable measures with you. With reference to article 33 of the REACH ordinance we inform you about the following:

An up-to-date list of candidates (updated June 20th, 2016, last checked for topicality December 20th, 2016) 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 %.

Moenchengladbach, 2016-12-20
(Place and date of the exhibit)

Thomas Hollex
(Issuer)


(Signature)



Management System
EN ISO 13485:2012
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