



DECLARATION OF CONFORMITY

MCD Medical Line AESCU.nano

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| 2000063M | MCD Medical Line AESCU.nano |
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MCD Medical Computers Deutschland GmbH
Konrad-Zuse-Ring 17 A/B
41179 Moenchengladbach
- Germany -

hereby declares 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:

IEC 60601-1-2:2014
EN 61000-4-2:2009, EN 61000-4-3:2011, EN 61000-4-4:2013, EN 61000-4-6:2014

Power Supply:

FSP-Group: FSP090-RHCM1

IEC 60601-1-2, EN 61000-3-2, EN 61000-3-3, EN 61000-4-2, EN 61000-4-3, EN 61000-4-4, EN 61000-4-5, EN 61000-4-6, EN 61000-4-8, EN 61000-4-11, EN 55011

UL ES 60601-1, CSA C22.2 No. 60601-1, TÜV EN 60601-1

Bicker, BET-1012M

EN 60601-1-2: 2015 Klasse B, EN55011: 2009+ A1: 2010 Klasse B, IEC 61000-3-2: 2014 Klasse A, EN 61000-3-3: 2013, EN 60601-1: 2006 + A11 + A1 + A12

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.





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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) / (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 7th, 2017, last check for topicality November 1st, 2016) in accordance with article 59 (1, 10) of the ordinance (EC) no. 1907/2006 (REACH) was published.

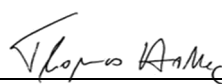
The mentioned above products and their packaging do not contain any substances of this current list of candidates in concentrations of more than 0.1 mass %.

Mönchengladbach, 21.01.2020

(Place and date of issue)

Thomas Hollex

(Signer)



(Sign)

