

Wissembourg, 25 FEB 2021

RoHS II / REACH 1907/2006/EU Declaration of Conformity

Referring to the Directive 2011/65/EU, amended by 2015/863/EU on the restriction of the use of certain hazardous substances (RoHS) in Medical Electrical and Electronic Equipment, and Regulation 1907/2006/EU, at the date of 25 Feb 2021, we declare the conformity of the Device:

DEFIGARD Touch7, and associated accessories (according the list referenced in the user manual).

The status of compliance with the RoHS II directive is specified; this status is defined compliant, as it doesn't contain the restricted substances above the official maximum concentration value.

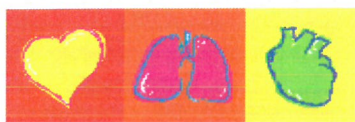
Restricted substances and maximum concentration values tolerated by weight in homogeneous materials:	
Lead (Pb)	0,1% by weight in homogeneous materials *
Mercury (Hg)	0,1% by weight in homogeneous materials
Cadmium (Cd)	0,01% by weight in homogeneous materials
Hexavalent chromium (Cr(VI))	0,1% by weight in homogeneous materials
Polybrominated biphenyls (PBB)	0,1% by weight in homogeneous materials
Polybrominated diphenyl ethers (PBDE)	0,1% by weight in homogeneous materials
Phtalate de bis-(2-éthylhexyle) (DEHP)	0,1% by weight in homogeneous materials
Phtalate de benzyle et de butyle (BBP)	0,1% by weight in homogeneous materials
Phtalate de dibutyle (DBP)	0,1% by weight in homogeneous materials
Phtalate de diisobutyle (DIBP)	0,1% by weight in homogeneous materials

*Homogeneous material' means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.

The status of compliance to REACH Regulation is specified according list updated in January 2021.

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THE ART OF DIAGNOSTICS