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ROHS & REACH STATEMENTS AND SUBSTANCE DECLARATION - FECG LEGPLATES

Manufacture information

Manufacture name	Neoventa Medical AB
Address	Norra Ågatan 32 431 35 Mölndal, Sweden
Contact person	Johan Sundberg, CQRO

Device information

Name	FECG Legplate Adapter for Neoventa, FECG Legplate Adapter for Philips
Art no	ACC300110, ACC300120
Basic UDI-DI	7340154900018Z
Class	I

RoHS statement

Based on the information presented in this document, we confirm that the materials used in the FECG Legplates, to the best of our knowledge, do not contain any of the restricted substances listed under the RoHS 3 directive 2011/65 (incl. 2015/863 and additional amendments) in concentrations exceeding the allowable limits. The sourcing and manufacturing processes are compliant with all relevant regulations to ensure the health and safety of end users.

REACH statement

Based on the information presented in this document, we confirm that the FECG Legplates, to the best of our knowledge, are compliant with the REACH Regulation (EC 1907/2006). We have assessed all relevant substances used in our products' composition and confirm that no substances of very high concern (SVHC) are present above the threshold levels specified by the regulation.

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RoHS 3 directive 2011/65 (incl. 2015/863 and additional amendments) restricted substances

Substance	Threshold value (%)	Present above threshold value Yes/No	If yes, material mass	If yes, information on where it is used
Cadmium	0.01	No	N/A	N/A
Lead	0.1	No	N/A	N/A
Mercury	0.1	No	N/A	N/A
Hexavalent chromium	0.1	No	N/A	N/A
Polybrominated biphenyls (PBB)	0.1	No	N/A	N/A
Polybrominated diphenyl ethers (PBDE)	0.1	No	N/A	N/A
Bis(2-ethylhexyl) phthalate (DEHP)	0.1	No	N/A	N/A
Butyl benzyl phthalate (BBP)	0.1	No	N/A	N/A
Dibutyl phthalate (DBP)	0.1	No	N/A	N/A
Diisobutyl phthalate (DIBP)	0.1	No	N/A	N/A

Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

The European Union´s REACH regulation addresses the production and use of chemicals substances and their potential impacts on human health and the environment.

REACH Articles 6 and 7 Registration and Notification

The FECG Legplates manufactured by Neoventa does not require substance registration and notification under REACH article 6 and 7.

REACH Article 33 (1) Information obligation

Article 33(1) requires suppliers to inform if any article contains more than 0.1% by weight per article of any substance(s) on the Substances of Very High Concern (SVHC) Candidate list. To Neoventa's best knowledge, there are not SVHC presented above 0.1% by weight in the FECG Legplates.

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REACH Article 67 Substance Restrictions

REACH article 67 specifies that substances restricted in REACH Annex XVII should not on its own, in a mixture or in an article be placed on the marked or used unless it complies with the conditions of that restriction.
To Neoventa's best knowledge, the FECG Legplates does not contain more than allowable limits of any of the substances listed in Annex XVII.

Medical Device Regulation (EU) 2017/745 (MDR)

MDR regulates the use of carcinogenic, mutagenic, or toxic to reproduction (CMR), and/or endocrine-disrupting substances. As per MDR, medical devices can not contain CMR and/or endocrine-disrupting substances in a concentration above 0.1% weight by weight/components. To Neoventa's best knowledge, the FECG Legplates does not contain any of those substances above 0.1% weight.

Latex free statement

The FECG Legplates and their product containers are not made with natural rubber latex.

Neoventa Medical AB

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Title: CQRO
Date: 2025-06-10
Signature:

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