Biocompatibility Statement

Product: MedEco XPI C3
Manufacturer/Supplier: BIOVOX GmbH
Date: 2026-04-01

Samples of the product have undergone a biocompatibility evaluation, with samples sterilized by gamma irradiation and/or ethylene oxide. The assessment focused on general risk assessment, chemical characterization, cytotoxicity of the composition and/or critical components according to the following standards:

- ISO 10993-1:2018 – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-18:2020 – Part 18: Chemical characterization of medical device materials within a risk management process

Biocompatibility (according to the statement and tests above) has been confirmed as acceptable based on the prescribed test requirements of the standards, showing a grade of zero reactivity and no biological response.

However, these biocompatibility tests are not part of a continuous production protocol.

The manner in which the product, technical support and information (verbal, written or through evaluations) are used is beyond our control. Therefore, the information provided in this statement is for reference only and is accurate to the best of our knowledge. It is the responsibility of our customers to inspect and test the product for its intended use, compliance and suitability.

Notice: BIOVOX has not obtained any approvals or licenses for specific product uses unless expressly stated. We make no warranty, express or implied, regarding the suitability of the above product for use in any medical device or pharmaceutical application. Changes to the above standards after the date of this statement invalidate this statement.

Sincerely,

Dr.-Ing. Vinzenz Nienhaus
BIOVOX GmbH

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