EC Declaration of Conformity

in accordance with EC Directive 93/42/EEC concerning medical devices.

Technologie Institut Medizin GmbH (TIM),
August - Thyssen - Str. 30, 56070 Koblenz, Germany

herewith declares under own responsibility as manufacturer that the Design, Construction and Version of the following Medical Device meet the Requirements of the European Directive 93/42/EEC.

Product identification:	**AR-PH**
Medical Device Trade Name:	**ARKON-PH**
Product description:	**Data bridge for MIRUS to PDMS**
Medical Device Class:	**Class I according to MDD 93/42/EEC rule 11 Annex IX**
Validity:	**This Declaration of Conformity is valid until 2024-01-20.**

The manufacturer's Quality Management System has been approved in accordance with DIN EN ISO 13485: 2016 by the Notified Body TÜV NORD CERT GmbH Langemarckstr. 20, 45141 Essen, Germany, Reg.No. 44 221 10 117873.

Any modification to the Product not authorized by TIM GmbH will invalidate this declaration.

Koblenz, 2019-12-04

Prof. Ing. Thomas P. Kriesmer
General Manager

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