

Statement for Class I Medical Device under MDD 93/42/EEC that is no longer a Medical Device under MDR 2017/745.

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declares as manufacturer that, according to the new definition of a medical product under MDR 2017/745, the product described below is no longer a medical product. Since 26th of May 2021 this product described below is a technical product used in a combination with a medical product without direct contact or impact to a patient

Product identification: AR-PH

Device Trade Name: ARKON – PH

Product description: Data bridge for MIRUS to PDMS

Koblenz, 2021-05-21

Prof. Ing. Thomas P. Kriesmer

General Manager

