

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:

**BA-ISO-K
BA-SEV-K
BA-SEV-Q
BA-SEV-SV
BA-SEV-PCC
BA-DES-S**

Device Trade Name:

MIRUS Bottle adapter

Product description:

Bottle Filling adapter to MIRUS Controller

Koblenz, 2021-05-21



Prof. Ing. Thomas P. Kriesmer
General Manager