

EC Declaration of Conformity

The Company:

Andreas Fahl Medizintechnik-Vertrieb GmbH
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51149 Köln, Germany
SRN: DE-MF-000006665

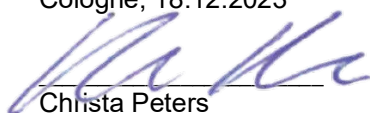
hereby account for the medical devices listed in the annex on which this declaration is based, that they conform to the following EC legislation:

Regulation (EC) 2017/745 of 05 April 2017, Medical Device Regulation (MDR)

Product group	OPTIBRUSH Basic
Basic UDI-DI	405194831800OPTIBRUSHZBCH
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Classification Rule	1
REFs / Medical Devices	see annex on next page
Intended purpose	The OPTIBRUSH®, OPTIBRUSH® Basic & OPTIBRUSH® PLUS is a special brush for gentle cleaning of tracheal cannulas.
Conformity assessment procedure	Medical devices listed in the annex conform to "general safety and performance requirements" according to EC regulation 2017/745, Annex I. The conformity of medical devices is declared based on technical documentation according to EC regulation 2017/745, Annex II and III. The manufacturer assumes sole responsibility for compliance with the requirements of EC regulation 2017/745 and all other Union legislation applicable to the medical devices listed in the annex below.

This Declaration of Conformity applies to all devices supplied after the production date until further notice. In the event of changes for the conformity assessment procedure, device alterations and changes to normative or regulatory requirements, conformity will be re-evaluated and declared again.

Cologne, 18.12.2023



Christa Peters

Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
31800-06	OPTIBRUSH® Basic SIZE 6
31800-08	OPTIBRUSH® Basic SIZE 8
31800-10	OPTIBRUSH® Basic SIZE 10
31800-12	OPTIBRUSH® Basic SIZE 12
31850-04	OPTIBRUSH® SIZE 4
31850-05	OPTIBRUSH® SIZE 5
31850-06	OPTIBRUSH® SIZE 6
31850-07	OPTIBRUSH® SIZE 7
31850-08	OPTIBRUSH® SIZE 8
31850-09	OPTIBRUSH® SIZE 9
31850-10	OPTIBRUSH® SIZE 10
31850-11	OPTIBRUSH® SIZE 11
31850-12	OPTIBRUSH® SIZE 12
31850-13	OPTIBRUSH® SIZE 13
31850-14	OPTIBRUSH® SIZE 14
31855-05	OPTIBRUSH® PLUS SIZE 5
31855-06	OPTIBRUSH® PLUS SIZE 6
31855-07	OPTIBRUSH® PLUS SIZE 7
31855-08	OPTIBRUSH® PLUS SIZE 8
31855-09	OPTIBRUSH® PLUS SIZE 9
31855-10	OPTIBRUSH® PLUS SIZE 10
31855-11	OPTIBRUSH® PLUS SIZE 11
31855-12	OPTIBRUSH® PLUS SIZE 12
31855-14	OPTIBRUSH® PLUS SIZE 14
31910	OPTIBRUSH® SWAB
31920	OPTIBRUSH® SWAB XL
31925	OPTIBRUSH® SWAB XL - LENGTH 25 cm