

EC Declaration of Conformity

The Company:

Andreas Fahl Medizintechnik-Vertrieb GmbH
August-Horch-Straße 4a
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	30000 - Tracheal Compresses 7000494
Basic UDI-DI	405194830000TC7000494KPCA
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Classification Rule	4
REFs / Medical Devices	see annex on next page
Intended purpose	Tracheal compresses serve to absorb tracheal secretions and to cushion the tracheal neck flange against the skin.
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, 12.12.2024


Christa Peters

Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
30000	SENSOTRACH® ALU 8 x 10 cm
30010	SENSOTRACH® ALU 8 x 10 cm
30030	SENSOTRACH® ALU SLIT 8 x 10 cm
30036	SENSOTRACH® ALU SLIT 8 x 9 cm
30520	SENSOTRACH® UNO 9 x 9,8 cm
30521	SENSOTRACH® UNO SLIT 9 x 9,8 cm
30522	SENSOTRACH® UNO PED 6 x 7 cm
30523	SENSOTRACH® UNO PED SLIT 6 x 7 cm
30524	SENSOTRACH® UNO PED ALU SLIT 6 x 7 cm
30525	SENSOTRACH® UNO PED SLIT Junior
30608	SENSOTRACH® DUO 9 x 9,8 cm
30609	SENSOTRACH® DUO SLIT 9 x 9,8 cm
30622	SENSOTRACH® DUO PED, 6 x 7 cm
30623	SENSOTRACH® DUO PED SLIT, 6 x 7 cm
30662	SENSOTRACH® DUO ALU 9 x 9,8 cm
30663	SENSOTRACH® DUO ALU SLIT 9 x 9,8 cm
30668	SENSOTRACH® DUO SKIN 9 x 9,8 cm
30669	SENSOTRACH® DUO SKIN SLIT 9 x 9,8 cm
30770	SENSOTRACH® 3-Plus 9 x 9,8 cm
30780	SENSOTRACH® 3-Plus SLIT 9 x 9,8 cm
30000	SENSOTRACH® ALU 8 x 10 cm
30010	SENSOTRACH® ALU 8 x 10 cm
30030	SENSOTRACH® ALU SLIT 8 x 10 cm
30036	SENSOTRACH® ALU SLIT 8 x 9 cm
30520	SENSOTRACH® UNO 9 x 9,8 cm
30521	SENSOTRACH® UNO SLIT 9 x 9,8 cm
30522	SENSOTRACH® UNO PED 6 x 7 cm
30523	SENSOTRACH® UNO PED SLIT 6 x 7 cm
30524	SENSOTRACH® UNO PED ALU SLIT 6 x 7 cm
30525	SENSOTRACH® UNO PED SLIT Junior
30608	SENSOTRACH® DUO 9 x 9,8 cm

REF	Medical Device
30609	SENSOTRACH® DUO SLIT 9 x 9,8 cm
30622	SENSOTRACH® DUO PED, 6 x 7 cm
30623	SENSOTRACH® DUO PED SLIT, 6 x 7 cm
30662	SENSOTRACH® DUO ALU 9 x 9,8 cm
30663	SENSOTRACH® DUO ALU SLIT 9 x 9,8 cm
30668	SENSOTRACH® DUO SKIN 9 x 9,8 cm
30669	SENSOTRACH® DUO SKIN SLIT 9 x 9,8 cm
30770	SENSOTRACH® 3-Plus 9 x 9,8 cm
30780	SENSOTRACH® 3-Plus SLIT 9 x 9,8 cm