ANDREAS FAHL
MEDIZINTECHNIK-VERTRIEB GMBH

August-Horch-Straße 4a
51149 Köln, Germany

Telefon +49(0)2203/2980-0
Telefax +49(0)2203/2980-100
mail vertrieb@fahl.de
www.fahl.de

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 directive:

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD)

Product group	SENSOFOAM®
Basic UDI-DI	405194830860TRACHH+KPSTR3
Class acc. to Directive 93/42/EEC	Class Is
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 "essential requirements" of this directive as per Annex I. Conformity of the medical devices to Directive 93/42/EEC is declared as per Annex II. The manufacturer assumes sole responsibility for compliance with the requirements of Directive 93/42/EEC and all other Union legislation applicable to the medical devices listed in the annex below.

The manufacturer is subject to supervision by the notified body:
DNV MEDCERT GmbH (CE 0482), Pilatuspool 2, 20355 Hamburg, Germany

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, 27.05.2024

Andreas Fahl
Medizintechnik-Vertrieb GmbH
August-Horch-Straße 4a
D-51149 Köln (Porz-Grengelbergbrücken)
Telefon: + 49 (0) 2203 / 29 80 - 0
Telefax: + 49 (0) 2203 / 29 80 - 100

p.p. Christoph Bernads
Quality Management, Andreas Fahl Medizintechnik-Vertrieb GmbH

ANDREAS FAHL
MEDIZINTECHNIK-VERTRIEB GMBH

August-Horch-Straße 4a
51149 Köln, Germany

Telefon +49(0)2203/2980-0
Telefax +49(0)2203/2980-100
mail vertrieb@fahl.de
www.fahl.de

Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
30860	SENSOFOAM® - sterile 10 x 9 x 0,5 cm
30861	SENSOFOAM® SMALL - sterile 6,5 x 6,5 x 0,5 cm
30862	SENSOFOAM® PAD - sterile 7,8 x 3,8 cm
30864	SENSOFOAM® PAD professional sterile, 7,8 x 3,8 cm