ANDREAS FAHL
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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	LARYNGOTEC® PRO
Basic UDI-DI	405194814722LGTPRO+++TKNE
Class acc. to Directive 93/42/EEC	Class IIb
Classification Rule	5
REFs / Medical Devices	see annex on next page
Intended purpose	FAHL® tracheostomy tubes are intended to stabilise the tracheostomy following laryngectomy or tracheotomy. The tracheostomy tube is designed to keep the tracheostomy open. Tracheostomy tubes with cuff can be used for mechanical ventilation, including under anaesthesia. Percutec variants are designed for additional use in percutaneous dilatation tracheostomy.
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

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

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Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
14722-0836	LARYNGOTEC ® PRO KOMBI LINGO Size 08/36
14722-0855	LARYNGOTEC ® PRO KOMBI LINGO Size 08/55
14722-0936	LARYNGOTEC ® PRO KOMBI LINGO Size 09/36
14722-0955	LARYNGOTEC ® PRO KOMBI LINGO Size 09/55
14722-1036	LARYNGOTEC ® PRO KOMBI LINGO Size 10/36
14722-1055	LARYNGOTEC ® PRO KOMBI LINGO Size 10/55
14722-1236	LARYNGOTEC ® PRO KOMBI LINGO Size 12/36
14722-1255	LARYNGOTEC ® PRO KOMBI LINGO Size 12/55
14825-0836	LARYNGOTEC ® PRO KOMBI CLIP LINGO SIZE 8/36
14825-0855	LARYNGOTEC ® PRO KOMBI CLIP LINGO SIZE 8/55
14825-0936	LARYNGOTEC ® PRO KOMBI CLIP LINGO SIZE 9/36
14825-0955	LARYNGOTEC ® PRO KOMBI CLIP LINGO SIZE 9/55
14825-1036	LARYNGOTEC ® PRO KOMBI CLIP LINGO SIZE 10/36
14825-1055	LARYNGOTEC ® PRO KOMBI CLIP LINGO SIZE 10/55
14825-1236	LARYNGOTEC ® PRO KOMBI CLIP LINGO SIZE 12/36
14825-1255	LARYNGOTEC ® PRO KOMBI CLIP LINGO SIZE 12/55
14835-0836	LARYNGOTEC ® PRO KOMBI CLIP SIZE 8/36
14835-0855	LARYNGOTEC ® PRO KOMBI CLIP SIZE 8/55
14835-0936	LARYNGOTEC ® PRO KOMBI CLIP SIZE 9/36
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