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 legislation:

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

Product group	COMBIPHON®
Basic UDI-DI	405194827131CP+++++SVO2CD
Class acc. to EC regulation 2017/745 Annex VIII	Class IIa
Classification Rule	2
REFs / Medical Devices	see annex on next page
Intended purpose	The speaking valves enable spontaneously breathing tracheotomised patients with a partially or fully preserved larynx to speak without having to use their fingers if a phonation cannula in combination with a fenestrated inner cannula or a tracheostomy patch is present. Speaking valves with an O2 connection also allow for the supply of additional oxygen via the integrated O2 connection.
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 according to EC regulation 2017/745, Annex IX. Certificate No.: 1320GB448260630 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.

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, 07.07.2026

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Christoph Bernads
Person Responsible for Regulatory Compliance

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Annex to EC Declaration of Conformity: List of Medical Devices

REF	Medical Device
27132	COMBIPHON® O2
27132-02	COMBIPHON® O2 blue