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 legislation:

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

Product group	FAHL® Hand Fix
Basic UDI-DI	405194832470HANDFIX++VA7Y
Class acc. to EC regulation 2017/745 Annex VIII	Class I
Classification Rule	1
REFs / Medical Devices	see annex on next page
Intended purpose	FAHL® Hand Fix are used as an aid for restraining patients at risk of acute self-harm once other measures have been exhausted.
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, 03.06.2024

Christa Peters

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
32470	FAHL® Hand Fix NEO, 3 x 12 cm
32472	FAHL® Hand Fix PED, 4 x 17 cm
32482	FAHL® Hand Fix, 7 x 25 cm
32485	FAHL® Hand Fix L, 7 x 30 cm