IVF HARTMANN AG
Victor-von-Bruns-Strasse 28
Postfach 634
CH-8212 Neuhausen

+41 52 674 31 11
+41 52 672 74 41
info@ivf.hartmann.info
ivf.hartmann.info

HARTMANN
Helps. Cares. Protects.

EU-Declaration of Conformity

Neuhausen, 16th December 2021

We herewith declare,

Object of declaration: TRAUMA BANDAGE (3207) (scope see Table 1)

which was first placed on the market by IVF HARTMANN AG, meets the applicable provisions, in particular the General Safety and Performance Requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The Conformity Assessment Procedure according to Article 52 (7) and according to Annex XI part A (Cert No G21 047326 0010) with respect to sterility has been performed and the Technical Documentation is kept available.

This EU-Declaration of Conformity is issued under the sole responsibility of the IVF HARTMANN AG.

The sterilization Processes are under the supervision of the Notified Body:

TÜV SÜD Product Service GmbH, Riedlerstr. 65, 80339 München, Germany, ID-Nr. 0123.

The product has been identified as a medical device in risk class Is according to Rule 4 indent 1 in Annex VIII of Regulation (EU) 2017/745.

High-level Intended Purpose: Non-active, non-implantable devices for wound and skin care

Basic UDI-DI: 76116003207MC

EU Single Registration Number: CH-MF-000015962

CH Single Registration Number: CHRN-MF-20000305

European Representative: PAUL HARTMANN AG, Paul-Hartmann-Strasse 12, 89522 Heidenheim, Germany

IVF HARTMANN AG:

i.V. Susanne Frei
Teamleader Regulatory Affairs

This document is valid until: 2026-12-15

Translation available at / Übersetzung verfügbar unter / Traduction disponible à / Traduzione disponibile su: http://www.ivf.hartmann.info/certificate

IVF HARTMANN AG
Victor-von-Bruns-Strasse 28
Postfach 634
CH-8212 Neuhausen

+41 52 674 31 11
+41 52 672 74 41
info@ivf.hartmann.info
ivf.hartmann.info

HARTMANN
Helps. Cares. Protects.

Table 1: Scope

REF	Description
831273	TRAUMA Bandage 10 cm
831274	TRAUMA Bandage 15 cm
831275	TRAUMA Bandage 20 cm
831276	TRAUMA Bandage 10 cm AR