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

EU-Declaration of Conformity

Neuhausen, 23rd of April 2020

We herewith declare,

Object of declaration: Alginates (3206) (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) 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 product has been identified as a medical device in risk class 1 according to Rule 4 indent 1 and Rule 5 indent 2 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 76116003206MA

Single Registration Number: not yet available

European Representative (for REF 601510 only): PAUL HARTMANN AG, Paul-Hartmann-Strasse 12, 89522 Heidenheim, Germany

IVF HARTMANN AG:

i.V. Susanne Frei
Regulatory Affairs Senior Manager

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

Table 1: Scope

REF	Description
601510	DermaPlast Alginat Fl 2g
601610	Flawa Alginat Fl 2g