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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

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Table 1: Scope

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