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EU-Declaration of Conformity

Veverská Bítýška, 3. December 2020

We herewith declare,

Object of declaration: Dressing gauze cut (2588)

which has been first placed on the market by HARTMANN – RICO a.s., meets the applicable provisions, in particular, the General Safety and Performance of the following EU-legislation:

- 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.

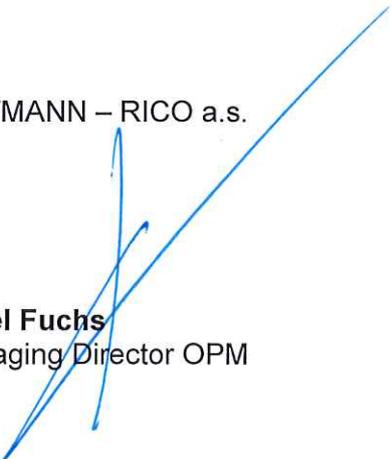
This EU-Declaration of Conformity is issued under the sole responsibility of the HARTMANN – RICO a.s.

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

Basic UDI-DI: 859500322588GK

Registration Number: CZ/ 00019924 (RZPRO)

HARTMANN – RICO a.s.


Pavel Fuchs
Managing Director OPM


Eva Bútorová
Regulatory Affairs & Service Manager