DINA-HITEX spol. s r.o., Ždánská 987, 685 01 Bučovice, Czech Republic
Tel +420 517 380 215, Fax +420 517 380 831, e-mail **info@dina-hitex.com**, **www.dina-hitex.com**

DECLARATION OF CONFORMITY

Under the European Directive 93/42 EEC as amended by 2007/47/EC

Manufacturer: Dina Hitex spol. s r.o.
Ždánská 987
Bučovice 685 01,
Czech Republic

Herewith declares under his sole responsibility that the product

Model: Hip drape 2SBL, 240x400cm with two integrated extremity covers, AP, IF.

DINA HITEX Ref: 301-641-S.

MedEnvision Ref: ME-ED1000

Class: I sterile

Is in conformity with applicable regulation:

Directive: MDD 93/42/EEC, Annex V

Quality Assurance Standards: EN ISO 13485:2016

Harmonized Standards:
EN ISO 10993-1:2009; EN ISO 10993-5:2009; EN ISO 10993-7:2008; EN ISO 10993-10:2013; EN ISO 11135: 2014; EN ISO 11138-2:2017; EN 11140-1:2014; EN ISO 11607-1:2017; EN ISO 11607-2:2017; EN ISO 11737-1:2018; EN ISO 11737-2:2009; EN ISO 14644-1:2015; EN ISO 14971:2012; EN 13795-1: 2019; EN 556-1:2001; EN 868-5:2018; EN ISO 15223-1:2016

Product is in conformity with Essential Requirements Annex I of Directive and is safe for declared use in standard conditions. Product is solely disposable.

Notify body: ELECTROTECHNICAL TESTING INSTITUTE, No. 1014

EC certificate no: MED 200022, valid until 26.05.2024

Bučovice, 15.02.2021

Pavel Hrabovský
Managing Director

Jiří Novotný
Regulatory Department