DINA - HITEX®

DECLARATION OF CONFORMITY

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

Manufacturer: Dina Hitex spol. s r.o.,
Zdanska 987
Bucovice 685 01
Czech Republic

Herewith declares under his sole responsibility that the products

Hitex – sterile disposable medical devices, class I sterile

are in conformity with applicable regulation:

Directive: MDD 93/42/EEC, Annex V

Quality Assurance Standards: EN ISO 13 485:2016

Procedural 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 ISO 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 ISO 15223-1:2016; EN 556-1:2001; EN 868-5:2018; EN 13795-1:2019; EN 14079:2003;

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

Notify body: ELECTROTECHNICAL TESTING INSTITUTE, NB No. 1014

EC certificate No.: MED 200022, valid until 26.05.2024

Bucovice, 14.05.2020

Pavel Hrabovský
ředitel

Jiří Novotný
úsek regulace