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 Pack – sterile procedural packs

a) Has verified the mutual compatibility of medical device in accordance with the manufacturers‘ instructions and has carried out his operations in accordance with these instructions.

b) Has packed the procedure pack of medical devices and supplied relevant information to users incorporating relevant instructions from the manufacturers.

c) Has ensured the implementation of all checking and control activities relevant to assembling, packaging and sterilization process in accordance with internal procedures of the company.

d) The sterilization has been carried out in accordance with the manufacturer’s instructions

Notify body: ELECTROTECHNICAL TESTING INSTITUTE, NB No. 1014

EC certificate No.: MED 200021, valid until 26.05.2024

Bucovice, 14.05.2020

Pavel Hrabovský
ředitel

Jiří Novotný
úsek regulace