

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC  
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHHECHISCHE REPUBLIK  
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE  
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod lisem 129/2, 171 02 Praha 8 - Troja

## EC CERTIFICATE PRODUCTION QUALITY ASSURANCE

issued in accordance with Annex 5 of Government Order No. 54/2015 Coll.  
(Annex V of Directive 93/42/EEC)

No.: MED 200022

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried audit results has decided that the quality system limited to the manufacturing aspects relevant to securing and maintaining sterile conditions established at the

manufacturer **DINA - HITEX, spol. s r.o.**  
**Ždánská 987, 685 01 Bučovice, Czech Republic**

for medical device(s)

**Hitex – sterile disposable medical devices, class I sterile - see enclosure**

meets the provisions of Annex 5 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex V of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. MED000084-04/01 of: 12.05.2020.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 5 clause 4 of Government Order No. 54/2015 Coll. (Annex V clause 4 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

Edition 1

The first issue of this Certificate from 14.05.2020 with validity until 26.05.2024

**The validity of this Certificate is limited until: 26.05.2024**

14.05.2020

Prague

Mgr. Miroslav Sedláček  
Head of Certification Body



MED000084-04