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**

Date: 07.04.2021 Revision: 1

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 product:

Sterile ophthalmic diagnostic strip

Class: **I sterile**

Type: **SCHIRMER-PLUS®**

Is in conformity with applicable regulation:

Directive:
MDD 93/42/EEC, Annex V

Quality Assurance Standards:
EN ISO 13 485:2016

Procedural Standards:
EN ISO 11135: 2014; EN ISO 11138-2:2017; EN ISO 11607-1:2020; EN ISO 11607-2:2020; EN ISO 11737-1:2018; EN ISO 11737-2:2020; EN ISO 14644-1:2015; EN ISO 14971:2019; EN 556-1:2001; EN ISO 868-5:2018; EN ISO 15223-1:2016; EN ISO 10993-7:2008; EN ISO 10993-5:2010; EN ISO 10993-10:2014

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

Notify body:
DNV Product Assurance AS, No. 2460

EC certificate No.:
10000452703-PA-NA-CZE rev. 0.0

Ing. Pavel Hrabovský
Managing Director

Ing. Jiří Novotný
Regulatory Affair