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

Date: 10.11.2023 Valid until: 10.11.2028 Revision: 2

EU Declaration of Conformity

Manufacturer:	DINA – HITEX, spol. s r.o. Ždánská 987 Bučovice, 685 01 Czech Republic
SRN:	CZ-MF-000000312
Product identification:	**Device covers**
Basic UDI-DI:	8591527000300ISPZ
Classification:	I sterile (Class 1, rule 1)
Notified Body:	3EC International a.s. Hraničná 18 821 05 Bratislava
NB Identification number:	2265
Conformity assessment route:	Chosen conformity assessment process as per Annex IX conformity assessment based on a quality management system and on assessment of technical documentation.

This declaration of conformity is issued under the sole responsibility of DINA-HITEX spol. s r.o. We hereby declare that the medical device(s) specified above meet the relevant provisions of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the EU Quality management system certificate issued by 3EC International a.s., certificate No. 2023-MDR/QS-050.

This EU declaration of conformity applies to the products listed in Annex I.

Ing. Pavel Hrabovský
Managing director

Ing. Jiří Novotný
Regulatory affairs

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

ANNEX I

Category	Group number	Content
Device covers	03	Camera covers
		C-arm covers
		Cord covers
		Mayo covers
		Other covers
		Probe covers

Intended purpose:

Device covers are intended to cover and isolate various types of devices and equipment and prevent mechanical and microbiological contamination. They prevent patients a medical professional's form disease, contamination, microorganisms, body fluids and particulate matter, therefore they maintain sterility of the operation area.