PRONELATEX projektové řízení výroby	**F 09-01 Prohlášení o shodě DECLARATION of CONFORMITY**	Počet stránek: 1 Index změn: 0

CERTIFICATE

DECLARATION OF CONFORMITY

According to Regulation of the European Parliament and of Council 93/42/EHS manufactured and placed on the market in accordance with technical standard
(EU) 2020/403 - PSA 2016/425 –EN 14683 Class1

Manufacturer PRONELATEX s.r.o

Declares that
Product

Respiratory mask NTF with filter
Ústenka NTF s filtrem

is in agreement
With Regulation 93/42/EHS of the European Parliament and of the Council, manufactured and placed on the market in accordance with technical standard
(EU) 2020/403 - PSA 2016/425 –EN 14683 Class1 and meets requirements for BFE
(Bacterial Filtration Efficiency for medical facemasks with repeated use) according standard
(EU) 2020/403 - PSA 2016/425 –EN 14683 and product is notified by State Institute for Drug Control (SÚKL)

aitex ENAC DEKRA CE **TYPE IR**

Asociación de Investigación de la Industria Textil – C.I.F.: G03182870
TEST REPORT : 2020TM2799
DEKRA Testing and Certification GmbH – Prufbericht Nr.3420005.10/20 PSA

SÚKL Státní ústav pro kontrolu léčiv State Institut for Drug Control

Ústenka NTF s filtrem
Notification: Register of Medical Devices Nr. 00926153, GMDN generic device group: 37713 Surgical/medical face mask, reusable

Manufacturer **Pronelatex s.r.o,** Národní 958, 55101 Jaroměř, CZ28858956,
CZ19/007 SGS ISO9001:2008
Registered manufacturer of medical devices: SÚKL Nr. 063140

SGS S 3231

Pronelatex s.r.o.
Národní 958, 551 01 JAROMĚŘ
IČ: 28858956
DIČ: CZ28858956

Vypracoval / podpis:	Ing.Jásenský	Datum:	28.2.2020
Schválil / podpis:	Ing.Jásenský	Datum:	28.2.2020