



Declaration of conformity No. EU-01

To the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Manufacturer Brand name	PI KRYVORUCHKO ROMAN PRO STERIL
Address	Vinnytsia, str. K. Vasylenko, building 6A, sq. 44, Ukraine
Manufacturing address	21000, Vinnytsia, str. Keletska, bldg. 117 b, Ukraine
EU Authorized Representative, address	GRONADA LTD Eisiskiy ave. 47-312 Vilnius, Lithuania +370 609 52385 / www.pro-steril.eu
SRN	LT-CA01/MDD/1-00048/23 LT-CA01/MDD/1-00044/23 LT-CA01/MDD/1-00045/23 LT-CA01/MDD/1-00046/23 LT-CA01/MDD/1-00047/23
Medical Device	Disposable sterilization pouches (UDI: 482027015SP0012J) Disposable sterilization rolls (UDI: 482027015SR0012Y)
Classification (MDR, VIII, Rule I)	<i>Class I (non-sterile, without measurement function)</i>
Applied Technical Regulation	<i>Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC Annex VIII, Rule 1</i>
GMDN	13735
Date of signing, version:	24 December 2022, Version 1
Declaration of conformity is valid until:	23 December 2027

24 December 2022, Vilnius, LT
(Place and date of issue)

Irena Urbanavičienė Director
First name, second name, position (signature)

