

EC CERTIFICATE
Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

No. 5-875-500-2001

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.

certifies that the manufacturer:

P.H.P.U. JANPOL Dorota Janicka
ul. Jerzego Michałowicza 29
02-495 Warszawa
Poland

for the products / product category:

Single-use medical devices: syringes, vaginal specula, Hydro-Colon-Therapy sets, drainage bottles type REDON

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex V.

Registry number of the related audit report: **NE/1056/2020**

This certificate is valid until **2024-05-26** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by NEOEMKI LLC. as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 2

First issued by the Directorate of Device Testing and Clinical Engineering (EMKI) on 24 January 2020.

Budapest, 2020-08-05


László Imre
Managing Director



EMKI 2526

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu

NEOEMKI

ATTACHMENT TO EC CERTIFICATE

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Additional information for Certificate No. 5-875-500-2001

The certificate is valid for the following manufacturing sites / facilities:

P.H.P.U. JANPOL Dorota Janicka
02-495 Warszawa, ul. Jerzego Michałowicza 29
97-403 Druzbice, Hucisko 16
Poland

The certificate is valid for the following products:

<i>Product name</i>	<i>Class</i>	<i>REF number</i>
Syringe of 50 ml Luer - Lock (transparent)	IIa	ST.50.02
Syringe of 50 ml Luer (transparent)	IIa	ST.50.01
Syringe of 50 ml Luer - Lock (amber)	IIa	SB.50.02
Syringe of 50 ml Luer (amber)	IIa	SB.50.01
Syringe of 50 (60) ml with catheter fitting	I sterile*	SC.50.01
Syringe of 140 (160) ml with catheter fitting and LUER connector	I sterile*	SC.140.01
Vaginal speculum (single-use sterile) size S, size M	I sterile*	WGS.01, WGS.02
Hydro - Colon - Therapy set	IIa	HCT.01
Drainage Redon bottle 150/200ml	I sterile*	BR-150/200S
Drainage Redon bottle 250/400ml	I sterile*	BR-250/400S
Drainage Redon bottle 200/350ml	I sterile*	PR-200/350S
Drainage Redon bottle 250/300ml	I sterile*	PR-250/300S

* Assessment was limited to aspects of manufacture concerned with assuring and maintaining sterile conditions.

Issue: 2

Date: 2020-08-05

First issued: 2020-01-24


László Imre
Managing Director



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