



CERTIFICATE

This is to Certify that the Management System of

Printex S.r.l.

Loc. Piombinara snc

City: Colleferro (RM) IT - Post Code: 00034, Italy

has been audited and found to comply with the requirements of:

ISO 13485:2016
(Medical Devices – Quality Management System)

For the Scope of activities described below:

**EN: Design, production of self-adhesive labels in roll with
sterilization indicating ink**

**IT: Progettazione, produzione di etichette autoadesive in rotolo
con inchiostro virante**

Certificate No.: IT98323H

<u>Date of initial registration</u>	<u>Date of this Certificate</u>	<u>Surv. audit on or before/ Certificate expiry</u>	<u>Recertification Due</u>
08 February 2023	08 February 2023	07 February 2024	07 February 2026

Validity of this certificate is subject to successful completion of surveillance audit on or before due date,
in case surveillance audit not conducted this certificate shall be suspended/cancelled.



Director

For verification and updated information concerning the present certificate visit to www.lmscert.com

This Certificate is the property of LMS Certification Limited and shall be returned immediately when demanded.



KAB-MC-04



LMS Certification Limited
Labrynth Business Centre, 43 Middle Hill Gate, Stockport,
Great Manchester, England-SK1 3DG
Phone :+44 208 935 5094
Company No.: 11029176
Visit :- www.lmscert.com
E-mail :- info@lmscert.com



LMS/FM/001/Q/REV06



CERTIFICATE

Tai patvirtina, kad valdymo sistema

Printex Srl

Loc. Piombinara snc

Miestas: Colleferro (RM) IT - Pašto Indeksas: 00034, Italija

buvo patikrintas ir nustatyta, kad jis atitinka šiuos reikalavimus:

ISO 13485:2016 (Medicinos prietaisai – kokybės valdymo sistema)

Toliau aprašyti veiklos sričiai:

LT: Lipniųjų etikečių ritinėlių su sterilizaciją nurodančio rašalu projektavimas, gamyba

IT: Progettazione, produzione di etichette autoadesive in rotolo con inchiostro virante

Sertifikato Nr.: IT98323H

Pirminės registracijos data

Šio pažymėjimo data

Surv. auditas arba anksčiau/ Sertifikato

Pakartotinis



vasario 08 d

2023 m. vasario 08

galiojimo laikas 2024 m.

sertifikavimo

vasario 7 d

terminas 2026 m.

vasario 7 d

For verification and updated information, please refer to the LMS Certification website: www.lmscert.com.
This Certificate is the property of LMS Certification Limited. It is valid only for the scope and conditions stated on the certificate. It is not to be used for any other purpose. It is subject to the terms and conditions of the LMS Certification Limited. It is not to be used for any other purpose. It is subject to the terms and conditions of the LMS Certification Limited.



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direktorius



LMS/FM/001/Q/REV06



SELF-DECLARATION OF CONFORMITY

Company Name : Printex s.r.l.

MDR Code : 2322848

Address : Loc. Piombinara s.n.c., Colleferro (RM) Italy

Phone : +39 06 977 0590

Fax : +39 06 977 0591

Web/Mail : www.printexsrl.com / medical@printexsrl.com

We declare that our **labels with Type 1 process indicator** are registered on the Ministry of Health's website with the MDR number 2322848 as class I medical devices and do not need a CE declaration due to the nature of the product.

Labels with steam indicator Basic UDI-DI 802256227NC
Labels with Eo indicator Basic UDI-DI 802256228NE
Labels with Vh2O2 indicator Basic UDI-DI 802256229NG

Relevant Harmonized Standards

EN ISO 13485:2016
EN ISO 9001:2015
EN ISO 14001:2015

Other Regulation, Legislation & Guidelines

This self-declaration of conformity is based on the Annex IV D. Lgs. 745/17.

Colleferro, 15/11/2023

A. Maurizio Gabrieli
Legal Representative



Printex
www.printexmedical.com
export@printexsrl.com

SAVĒ-ATITIKTIES DEKLARACIJA

Īmonēs pavadinimas: Printex s.r.l

MDR kodas: 2322848

Adresas: Loc. Piombinara s.n.c, Colleferro (RM) Italija

Tel: +39 06 977 0590

Faksas: +39 06 977 0591

Svetainē / paštas: www.printexsrl.com / medical@printexsrl.com

Pareiškiamo, kad mūsu etiketēs su 1 tipo proceso indikatoriumi yra registruotos Sveikatos apsaugos ministerijos svetainėje MDR numeriu 2322848 kaip I klasės medicinos prietaisai ir dėl gaminio pobūdžio CE deklaracijos joms nereikia.

Etiketēs su garų indikatoriumi Basic UDI-DI 802256227NC

Etiketēs su Eo indikatoriumi Basic UDI-DI 802256228NE

Etiketēs su Vh2O2 indikatoriumi Basic UDI-DI 802256229NG

Atitinkami darnieji standartai

EN ISO 13485:2016

EN ISO 9001:2015

EN ISO 14001:2015

Kiti reglamentai, teisės aktai ir gairės

Ši atitikties deklaracija yra pagrįsta IV D priedu. Lgs. 745/17.

Colleferro, 2023-11-15

A. Maurizio Gabrieli
Teisinis atstovas