



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 17 0113 QS/NB

The quality system of manufacturer

Contipro a.s.

Dolní Dobrouč 401, 561 02 Dolní Dobrouč, Czech Republic

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

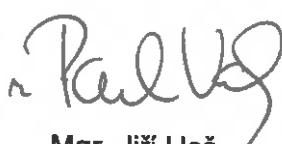
**Wound-nonadherent dressing, permeable, antimicrobial
Dressing, high-absorbent, liquid, hydrophilic gel-forming**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2021-05-18
Valid until: 2024-05-27
First Issued: 2017-04-19
Revision: d



Datum: 2021-05-18


Mgr. Jiří Heš
Representative of the Notified Body No. 1023



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INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 17 0113 QS/NB
issued for manufacturer:

Contipro a.s.
Dolní Dobrouč 401, 561 02 Dolní Dobrouč, Czech Republic

Product(s):

Name: **Wound-nonadherent dressing, permeable, antimicrobial**

Trade name(s): **Sorelex®**

Model(s): 7.5 x 7.5 cm (5 pcs; 10 pcs)
10 x 10 cm (1 pc; 5 pcs; 10 pcs)
12.5 x 12.5 cm (5 pcs; 10 pcs)
15 x 15 cm (5 pcs; 10 pcs)
10 x 20 cm (5 pcs; 10 pcs)

Class: III

GMDN: 47203

Name: **Dressing, high-absorbent, liquid, hydrophilic gel-forming**

Trade name(s): **Hyiodine®, Hyatoprol®, Anigran^{gel}**

Model(s): Hyiodine® (packaging 22 g, 50 g)
Hyatoprol® (packaging 22 g, 50 g)
Anigran^{gel} (packaging 50 g)

Class: III

GMDN: 43186

Date: 2021-05-18
Revision: d



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Facility(ies):

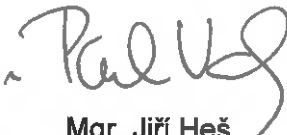
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Dolní Dobrouč 401, 561 02 Dolní Dobrouč, Czech Republic

Certificate History:

Revision	Date	Reference Number	Action
	2017-04-19	803602385	Certification
a	2018-06-29	803602554	Certification
b	2019-07-04	833600110	Correction of typing error in the product trade name Hyatoprol®
c	2020-03-03	803602837	Addition of one-piece packaging of product Sorelex®, model 10 x 10 cm
d	2021-05-18	803602877	Recertification



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