CONTIPRO

EC Declaration on Conformity

No. 03-21

Directive 93/42/EEC / Annex II / Full Quality Assurance System

Manufacturer	Contipro a.s.
Manufacturer´s Address	Dolní Dobrouč 401 561 02 Dolní Dobrouč Czech Republic

Medical Device Hyiodine®/Hyatoprol®/Anigran^{gel}

Description	Sterile medical device for coverage, cleaning and wound hydration
EC Product Class	Class III under Annex IX rules (Rule 13)
Package size	Hyiodine® 22 g, 50 g Hyatoprol® 22 g, 50 g Anigran^{gel} 50 g

Contipro a.s., as a manufacturer, hereby declares that the medical device Hyiodine®/Hyatoprol®/Anigran^{gel} meets the requirements of the EC Council Directive 93/42/EEC, as amended, and is in accordance with the Annex II of this directive.

Applied harmonised standards: EN ISO 9001:2015, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2016, EN 1041+A1:2013, EN 556-2:2016

Notified Body No.	1023
Address	Institute for testing and certification a.s. Třída Tomáše Bati 299, Louky, 763 02 Zlín Czech Republic VAT No. CZ47910381

The Notified Body No. 1023 has performed an audit of the product HYIODINE®/HYATOPROL®/Anigran^{gel} quality system according to Annex II covering the design, manufacture and final inspection of the certified product. After performed audit Notified Body No. 1023 issued the EC certificate No. 17 0113 QS/NB (issued on 19/04/2017 revision c from 15/08/2021) and EC design examination certificate No. 17 0114 CN/NB (issued on 19/04/2017 revision b from 15/08/2021).

This declaration of conformity is issued under the sole responsibility of legal manufacturer Contipro a.s.

Date 19. 05. 2021

Vladimír Velebný, PhD., Assoc. Prof.
General Manager

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