DECLARATION OF CONFORMITY

Manufacturer name and address: Unigroup ApS,
Diplomvej 373,
DK-2800 Lyngby, Denmark

Hereby we declare that the medical devices listed in the product list below, in the following product categories, complies with the applicable provisions of essential requirements and Council Directive 93/42/EEC, as amended by Directive 2007/47/EC, as well as applicable standards:

- Antifungal Treatment

The product(s) classification is mentioned in the Product list table accordingly.

This declaration is based on the implementation of a Quality Assurance System approved for the design, development, subcontracted manufacture and distribution of medical devices for topical use and packaging and distribution of IVD´s of the above mentioned product categories in accordance to the provisions of Annex V of Medical Device Directive 93/42/EEC. The certificate number 0425-MED-004444-00, initially issued on May 25, 2021 by ICIM, Sesto San Giovanni (MI), Italy, with Notified Body Identification Number 0425.
This declaration is supported by the Quality System certification based on the harmonized standard EN ISO 13485.

The device(s) does not incorporate, as an integral part, a medicinal product or human blood derivative. The devices are not manufactured utilizing tissues of animal origin.

Any unauthorized modification of the product without Unigroup's permission will invalidate this declaration.

This EU declaration of conformity is issued under the sole responsibility of Unigroup ApS.

The Declaration of Conformity is valid from the date of signature below.

Date and place: Lyngby, 25-05-2021

Signature:

Unigroup ApS
Flemming Licht
CEO

Product list A

This product list is part of the Declaration of Conformity (Document number: WTP-13-001.V04) issued by Unigroup ApS, and specifies the CE marked products that Unigroup ApS, manufactures and distributes in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC of 5 September 2007, concerning medical devices.

Device name	Classification	Basic UDI
Nilocin Nail Fungus Serum Pen	IIa, Rule 4	57064481010ANTIFUNGALDY
Nilocin Nail Fungus Ozone Treatment	IIa, Rule 4	57064481010ANTIFUNGALDY
Nilocin Nail Fungus Serum Brush Treatment	IIa, Rule 4	57064481010ANTIFUNGALDY
Nilocin Nail Fungus Treat & color	IIa, Rule 4	57064481010ANTIFUNGALDY
Nilocin Neglesvamp Serum Pen	IIa, Rule 4	57064481010ANTIFUNGALDY
Nilocin neglesvamp Ozone Pen	IIa, Rule 4	57064481010ANTIFUNGALDY
Protectair Fungal nail Treatment	IIa, Rule 4	57064481010ANTIFUNGALDY
Nilocin Athletes Foot Serum Spray	IIa, Rule 4	57064481010ANTIFUNGALDY

Revision Log

Revision	Author	Reason for Change	Changes
07	Flemming Licht	Change the format	- Addition of product list - New Notified Body information