



«NORMA» LLC
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EC DECLARATION OF CONFORMITY

Manufacturer
NORMA LLC.

Products
Sterilization Indicator Strips

Models:
Steam sterilization: "Sterilan 120/45"; "Sterilan 121/20"; "Sterilan 132/20"
Sterilization by dry heat: "Sterilan 160/150"; "Sterilan 180/60"
Sterilization in the package:
"Sterilan UP 120/45"; "Sterilan UP 121/20"; "Sterilan UP 132/20"
Sterilization by dry heat in the package: "Sterilan UP 180/60"

The product mentioned above conforms the requirements of Council Directive 93/42/EEC incl. amendment 2007/47/EC concerning medical devices. All related documents for products and conformity assessment procedure are kept in the manufacturer's facility.

Conformity assessment procedure
93/42/EEC incl. Annex VII

Classification
Class I Annex IX Rule 1

Standards Applied
EN ISO 11140-1:2009, IDT, ISO 11140-1:2005, IDT

Place & Date of Issue
Kyiv, Ukraine
September 5, 2022

Manufacturer/authorized representative
Kucher Sviatoslav

