



«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

