

CE DECLARATION OF CONFORMITY

The Manufacturer

GERARD WÓJCICKI
PRZEDSIĘBIORSTWO PRODUKCYJNE ANGER G&A

ul. Długa 64 A, 32-083 Szczyglice, Poland

declares under the sole responsibility that the devices covered by this Declaration of Conformity **are for single use only** and fulfil the requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 [MDR].

Device Name

Polyester Crown Forms (basic UDI-DI: 590761904001EK)

REF

Art.: 1-144.

Risk Class

Class I, Rule 5

This Declaration applies to the products with LOT numbers listed on the List of LOT numbers issued to the **Invoice no.:** EU/41/2022.

The conformity assessment is carried out according to the Annexes I + IV of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 [MDR].

Applicable Harmonised Standards:

PN-EN ISO 15223-1	PN-EN ISO 10993-5
PN-EN ISO 20417:2021	PN-EN ISO 10993-10
PN-EN ISO 14971	PN-EN ISO 9687
PN-EN ISO 13485	PN-EN ISO 3950
PN-EN ISO 10993-1	PN-EN 1639

Szczyglice, 01.08.2022

Place and date of issue

Gerard Wójcicki, Owner

Issued by