



EU DECLARATION OF CONFORMITY

The Manufacturer

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PRZEDSIĘBIORSTWO PRODUKCYJNE ANGER G&A

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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	Flexible P Scaler (basic UDI-DI: 590761904009F3)
REF	Art.: 1174, 1175, 1176, 1177
Risk Class	Class I, Rule 5 - According Annex VIII MDR
Medical Purpose	Tooth Reconstruction

This Declaration applies to the products with LOT numbers listed on the List of LOT numbers issued to the Invoice no.: EU/25/2026.

The conformity assessment is carried out according to the Annexes II + III 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, 25.05.2026

Place and date of issue



Gerard Wójcicki
CEO

Issued by