

EU DECLARATION OF CONFORMITY

The Manufacturer

GERARD WÓJCICKI
PRZEDSIĘBIORSTWO PRODUKCYJNE ANGER G&A

ul. Długa 64 A, 32-083 Szczyglice, Poland
SRN: PL-MF-000001898

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 M Scaler (basic UDI-DI: 590761904010EL)
REF	Art.: 1261, 1263, 1265, 1267, 1271, 1273, 1275, 1277
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