PRZEDSIĘBIORSTWO USŁUGOWO-HANDLOWE
"DENTEX" Sp. z o.o.
Opiesińska 30b
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DECLARATION OF CONFORMITY IN ACCORDANCE WITH REGULATION (EU) 2017/745

The President of PUH DENTEX Sp. z o. o. declares that

ACRYLIC TEETH DENTEX

Medical Dewvice Class I (Rule 5)

They comply with the provisions of the Council Regulation (EC) No. 2017/745 on medical devices, in accordance with the conformity assessment procedure described in Article 52, paragraph 7. - Declaration of product conformity (EU declaration of conformity + technical documentation specified in Annexes II and III.)

All supporting documentation is retained under the premises of **DENTEX sp. z o.o..**

The Manufacturer is exclusively responsible for the declaration of conformity

Harmonized Standards applied:

PN-EN ISO 13485:2016-04	Medical devices — Quality management systems — Requirements for regulatory purposes
PN-EN ISO 14971:2020-05	Medical devices — Application of risk management to medical devices
EN ISO 10993-1: 2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process.
PN-EN ISO 20417:2021-10	Medical devices — Information to be supplied by the manufacturer
PN-EN ISO 15223-1:2022-01	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
PN-EN 1641:2010	Dentistry - Medical devices for dentistry - Materials
PN-EN ISO 7405:2019-01	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

Technical standards ref:

PN-EN ISO 7491:2002	Dental materials — Determination of colour stability.
ISO 22112:2017 Dentistry	Artificial teeth for dental prostheses

Place: Zduńska Wola
Date: 25-04-2025
Signature:

Prezes Zarządu
Jarosław Basiel