Wytwórnia Zębów Sztucznych Wiedent Spółka Jawna
POLSKA, 94-104 Łódź, ul. Obywatelska 187/189
tel. +48 42 640 48 70, fax +48 42 688 33 84

EC DECLARATION OF CONFORMITY no 252/E

The undersigned Lidia Wieteska-Baron, Managing Director of WIEDENT,
herewith declares that the following range of products:

ESTETIC

Estetic "10V"- pink (shade 10) veined, Estetic "10" - pink (shade 10), Estetic "8V" - pink (shade 8) veined,
Estetic "8" - pink (shade 8), Estetic "0" - transparent
acrylic resin
intended for making removable dentures (complete and partial).
Medical Devices Class I (rule 5)
Kod Basic UDI-DI: 5907547710EsteticTA2G
SRN number: PL-MF-000029797
is in conformity with:

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC,
- EN ISO 14971:2019 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
- EN 1641:2009 Dentistry - Medical devices for dentistry – Materials,
- EN ISO 20795-1:2013 Dentistry — Base polymers — Part 1: Denture base polymers,
- EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements,
- EN ISO 20417:2021 Information supplied by the manufacturer,
- EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to Medical devices.

The conformity assessment is established in accordance with the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

WIEDENT declares that ESTETIC is manufactured in accordance with the technical documentation in accordance with Annexes II and III of the above Regulation.

WIEDENT has implemented the Full Assurance System certified against ISO 13485:2016 since 11 March 2003, which is supervised and audited by Notified Body SGS United Kingdom Ltd Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK - Certificate PL03/58618.

WIEDENT declares that the declaration is issued under its sole responsibility.

Place: Łódź

Date: 20.10.2022

Signature:

Lidia Wieteska-Baron

WYTWÓRNIA ZĘBÓW SZTUCZNYCH
Wiedent
L.Wieteska-Baron, L.Wieteski Spółka Jawna
94-104 Łódź, ul. Obywatelska 187/189
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NIP 727-10-19-908, Regon 471204321

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Signature:

Lidia Wieteska-Baron

DYREKTOR
Lidia Wieteska-Baron

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