

## EC DECLARATION OF CONFORMITY no 255/E

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

### ESTETIC S

Estetic S "10V"- pink (shade 10) veined, Estetic S "10" - pink (shade 10), Estetic S "8V" - pink (shade 8) veined,  
Estetic S "8" - pink (shade 8), Estetic S "0" - transparent  
Self-curing acrylic resin for repairing dentures and orthodontic bases  
Medical Devices Class I (rule 5)  
Kod Basic UDI-DI: 5907547710EsteticSTADK  
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 S 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:

DYREKTOR  
*Lidia Wieteska-Baron*  
Lidia Wieteska-Baron

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