

EC DECLARATION OF CONFORMITY no 264/E

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

ESTHETIC H

heat-curing acrylic resin for making temporary dentures (crowns and bridges)

Medical Devices Class I (rule 5)

Kod Basic UDI-DI: 5907547710EstheticHTAYT

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 22112:2017 Dentistry - Artificial teeth for dental prostheses
- 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 ESTHETIC H 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: 20.03.2023

Signature:

DYREKTOR

Lidia Wieteska-Baron