Certificate PL03/58619



The management system of

## Wytwórnia Zębów Sztucznych Wiedent Sp. J.

ul. Obywatelska 187/189, 94-104 Łódź, Poland



has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

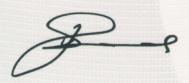
Design, manufacture and sale of artificial teeth for dentures and acrylic materials and waxes for prosthetic and dental purposes.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 11 March 2015 until 10 March 2018 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 11 January 2018 Issue 5. Certified since 11 March 2003

Authorised by



SGS United Kingdom Ltd Systems & Services Certification Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

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Certificate PL03/58618



The management system of

## Wytwórnia Zębów Sztucznych Wiedent Sp. J.

ul. Obywatelska 187/189, 94-104 Łódź, Poland

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

Design, manufacture and sale of artificial teeth for dentures and acrylic materials and waxes for prosthetic and dental purposes.

This certificate is valid from 11 June 2015 until 10 March 2018 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 11 January 2018 Issue 7. Certified since 11 March 2003

Authorised by



SGS United Kingdom Ltd Systems & Services Certification Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

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EC Certificate Full Quality Assurance System: Certificate PL03/58617



The management system of

## Wytwórnia Zębów Sztucznych Wiedent Sp. J.

ul. Obywatelska 187/189, 94-104 Łódź, Poland

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Wiedent ESTETIC acrylic teeth, ALMAMISS acrylic teeth, Estetic H heat-curing acrylic resin for crowns and bridges, Estetic Ekri opaquer.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 21 May 2015 until 11 March 2020 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 11 January 2018 Issue 9. Certified since 11 March 2003

Certification is based on reports numbered PL/WAW-PL00473

Authorised by



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