

vaš znak / your ref.:

OSV/1081

naš znak / our ref.:

2026-06-24

datum / date:

Mr. Dani Pečecnik  
POLIDENT d.o.o.  
Volčja Draga 42  
5293 VOLČJA DRAGA  
Slovenia

Dear Mr. Dani Pečecnik!

We would like to inform you that the Notified Body Commission for medical devices adopted the following decision at its last meeting:

On the basis of the submitted Notice of change MDR DN015, dated 2025-12-02, and post audit report (OSV 00599/2026, 2026-05-19), the current edition MDR-0014/05 of the Certificate, Detailed list of product names, models and types and Detailed list of relevant common specifications and standards is cancelled, and a new edition is issued:

EU certificate No.: **MDR-0014**

Issued to:	POLIDENT d.o.o. Volčja Draga 42, Slovenia
SRN of manufacturer:	SI-MF-000000740
Authorised representative:	Not applicable
SRN of authorised representative:	Not applicable

Legislative  
act/requirements: Regulation (EU) 2017/745  
Annex: IX

Device:	Materials for the preparation of custom-made dental devices – other
EMDN:	Q010699
Basic UDI-DI:	++EPOLPMMACCJ5
Classification:	Ila
Device:	Materials for the preparation of custom-made dental devices – other
EMDN:	Q010699
Basic UDI-DI code:	++EPOLPMMACCTTT
Classification:	Ila
Device:	Materials for the preparation of custom-made dental devices – other
EMDN:	Q010699
Basic UDI-DI code:	++EPOLPMMACCTCBTP
Classification:	Ila

Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI code: ++EPOLPINKCCJJ  
Classification: IIa

Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI code: ++EPOLPMMACCOS9E  
Classification: IIa

Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI: ++EPOLAPTKB  
Classification: IIa

Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI code: ++EPOLDBMJ2  
Classification: IIa

Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI code: ++EPOLCBMHV  
Classification: IIa

Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI code: ++EPOLORTOMHA  
Classification: IIa

Certification date: 2024-07-31  
Issue: 06/2026-06-24  
Valid until: 2029-07-30

Specific conditions or provisions or limitations and validity of certificate: /  
Identification Number of the Notified Body (1304) can be used in conjunction with EU certificate.  
Details of affixing CE marking are given in Article 20 of Regulation (EU) 2017/745 on medical devices.

The EU certificate (A4 paper format) is granted in English. EU certificate is enclosed in attachment. Also form for possible additional order of certificate is enclosed.

Detailed list of product names, models and types:

EU certificate No.: **MDR-0014**  
 Issued to: POLIDENT d.o.o.  
 Volčja Draga 42  
 SRN of manufacturer: SI-MF-000000740  
 Place of production: POLIDENT d.o.o.  
 Volčja Draga 42, 5293 Volčja Draga, Slovenija  
 Place of production: POLIDENT d.o.o.  
 Volčja Draga 41a, 5293 Volčja Draga, Slovenija  
 Authorised representative: Not applicable  
 SRN of authorised representative: Not applicable

Device: Materials for the preparation of custom-made dental devices - other

EMDN: Q010699

Intended Purpose: PMMA CAD/CAM discs are suitable:  
 - for milling of long-term temporary crowns and bridges  
 - for milling and verifying the appliance on the plaster model/mouth before the final ZrO<sub>2</sub> milling process;  
 - for milling the removable occlusal splint, and  
 - for milling of individual denture teeth, full arch and tooth segments to manufacture denture.

MDR code: MDN 1209

Classification: IIa

Basic UDI-DI: ++EPOLPMMACCJ5

Device name: PMMA CAD/CAM disc

Model/Type: PMMA CAD/CAM disc

Possible combinations are:

Form:

98,5 mm -shoulder

95 mm -ZZ

100 mm -AG\*

Shades:

Basic: A1, A2, A3, A3.5, B1, B2, B3, BL1, BL2, BL3, C2, D2, E1, E2, Clear, Berry\*\*, Blue\*\*, Green\*\*, Orange\*\*,

Multilayer: BL2, BL3, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, DE flag\*\*\*

Thickness:

Basic: 12, 14, 15, 16, 18, 20, 25, 30, 35 mm;

\* 100-AG not available in 12 mm.

\*\* only available in 16, 18, 20, 25, 30 mm

Multilayer: 15, 16, 18, 20 mm

\*\*\* only available in 20 mm

All variants with UDI-DI are listed in OBR-PD-85 List of devices.

Device name: ORGANIC PMMA eco

Model/Type: ORGANIC PMMA eco

Possible combinations are:

Form: 98,5 mm -shoulder, 120 mm- shoulder\*\*\*

Shades: Basic: A1, A2, A3, A3.5, B1, B2, B3, Clear\*, Berry\*\*, Blue\*\*, Green\*\*, Orange\*\*,

Multilayer: BL2, BL3, A1, A2, A3, A3.5, A4, B1, B3, B4, C1, C2, C3, C4, D2, D3, D4, DE flag\*\*

Thickness: Basic: 16, 20 mm

\* available also in 25 mm

\*\* only available in 20 mm

Multilayer: 15, 18, 20 mm

\*\*\* 120 mm discs are available only as clear variants in thicknesses of 16 and 20 mm

All variants with UDI-DI are listed in OBR-PD-85 List of devices.

Device name: DEGOS L-Temp MultiColor

Model/Type: DEGOS L-Temp MultiColor

Possible combinations are:

Form: 98,5 mm -shoulder, 95 mm – ZZ

Shades: Multilayer - BL2, BL3, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4

Thicknesses: Multilayer - 16, 20 mm

All variants with UDI-DI are listed in OBR-PD-85 List of devices.

Device: Materials for the preparation of custom-made dental devices – other

EMDN: Q010699

Intended Purpose: PALA Mill&Cast Teeth:

suitable for milling full tooth arch to manufacture denture.

MDR code: MDN 1209

Classification: IIa

Basic UDI-DI: ++EPOLPMMACCTTT

Device name: PALA Mill&Cast Teeth

Model/Type: PALA Mill&Cast Teeth

Form: 98,5 mm (Kulzer exclusive form)

Shades: Basic: A2 – A3 – A3,5

Thickness: full height of disc: 35 mm / tooth part height: 15mm

All variants with UDI-DI are listed in OBR-PD-85 List of devices.

Device: Materials for the preparation of custom-made dental devices – other

EMDN: Q010699

Intended Purpose: DD poly Y ML:

suitable for milling:

- long-term temporary crowns and bridges,

- individual denture teeth, full arch and tooth segments to manufacture denture

MDR code: MDN 1209

Classification: IIa

Basic UDI-DI: ++EPOLPMMACCTCBTP

Device name: DD poly Y ML

Model/Type: DD poly Y ML  
Possible combinations are:  
Form: 98,5 mm-shoulder  
Shades: Multilayer: 0M2\*, 0M3\*\*, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4  
\*0M2 = BL2; \*\*0M3 = BL3  
Thickness: Multilayer: 16, 20 mm  
All variants with UDI-DI are listed in OBR-PD-85 List of devices.

Device: Materials for the preparation of custom-made dental devices – other

EMDN: Q010699

Intended Purpose: Pink CAD/CAM discs are suitable for:  
- milling full and partial dentures and temporary immediate load implant supported dentures

MDR code: MDN 1209

Classification: IIa

Basic UDI-DI: ++EPOLPINKCCJJ

Device name: Pink CAD/CAM disc

Model/Type: Pink CAD/CAM disc

Possible combinations are:

Form:

Basic:

98,5 mm-shoulder

95 mm-ZZ

100 mm-AG

Multilayer:

98,5 mm-shoulder

95 mm-ZZ

100 mm-AG

Shades:

Basic: Pink, Pink veined

Multilayer: G71, G74 (multilayer)

Thickness:

Basic: 20, 25, 27, 30, 35, 40 mm

Multilayer: 20, 25, 27, 30, 35, 40 mm

All variants with UDI-DI are listed in OBR-PD-86 List of devices  
Pink discs.

Device name: PALA Mill Base

Models/Type: PALA Mill Base

Possible combinations are:

Form:

98,5 mm-shoulder

Shades\*:

Pink (1), Pink live (34)

\* shades were developed exclusively for Kulzer, on the base on Pink CAD/CAM discs within the same pigment composition.

Thickness:

30 mm

All variants with UDI-DI are listed in OBR-PD-86 List of devices  
Pink discs.

Device name ORGANIC PMMA FD  
 Models//Type: ORGANIC PMMA FD  
 Possible combinations are:  
 Form:  
 98,5 mm-shoulder  
 Shades:  
 Basic: pink, pink geadert\*  
 \* pink geadert = pink veined  
 Multilayer: light\*\*, dark\*\*  
 \*\*light = G71; dark = G74  
 Thickness:  
 Basic: 20, 25, 27, 30, 35, 40 mm  
 Multilayer: 20, 25, 30, 35, 40 mm  
 All variants with UDI-DI are listed in OBR-PD-86 List of devices  
 Pink discs.

Device name Zirlux Pink  
 Models//Type: Possible combinations are:  
 Form: 98,5 mm-shoulder  
 Shade: pink  
 Thickness: 25, 27, 30 mm  
 All variants with UDI-DI are listed in OBR-PD-86.

Device: Materials for the preparation of custom-made dental devices –  
 other  
 EMDN: Q010699  
 Intended Purpose: Zirlux PMMA Transparent are suitable for:  
 - milling the removable occlusal splint  
 MDR code: MDN 1209  
 Classification: IIa  
 Basic UDI-DI: ++EPOLPMMACCOS9E

Device name Zirlux PMMA Transparent  
 Models//Type: Possible combinations are:  
 Form: 98,5 mm-shoulder  
 Shades: Clear  
 Thickness: 14, 16, 18, 20, 25 mm  
 All variants with UDI-DI are listed in OBR-PD-85

Device: Materials for the preparation of custom-made dental devices –  
 other  
 EMDN: Q010699  
 Intended Purpose: Cross linked 2: Artificial teeth for replacing missing teeth by making  
 total and partial dentures  
 Primodent: Artificial teeth for replacing missing teeth by making  
 total and partial dentures.  
 Ref-Line: Artificial teeth for replacing missing teeth by making total  
 and partial dentures and by making implant supported dentures  
 MDR code: MDN 1209  
 Classification: IIa  
 Basic UDI-DI: ++EPOLAPTKB  
 Place of production RAFE DOOEL, EKSPORT-IMPORT,

Ulica 5 br. 9a, Novo selo, Gjorce Petrov, Skopje, N. Macedonia

Device name: Cross linked 2  
Model/Type: Cross linked 2, Type 1 (anterior)  
Cross linked 2, Type 2 (posterior)  
Basic, Type 1 (anterior)  
Basic, Type 2 (posterior)  
Basic is alternative name for Cross Linked 2  
Available forms:  
Upper anterior: 41, 42, 43, 44, 45, 01, 02, 03, 04, 05, 06, 31, 32,  
33, 34, 35, 36, 37,  
Lower anterior: I1, I2, I3, I4, I5, I6, I7,  
Posterior teeth: T1 upper, T1 lower, T2 upper, T2 lower, T3 upper,  
T3 lower, T4 upper, T4 lower, T5 upper, T5 lower, T6 upper, T6  
lower  
Available Shades:  
BL3,  
A1-A2-A3-A3,5-A4,  
B1-B2-B3-B4,  
C1-C2-C3-C4,  
D2-D3-D4  
All available combinations are listed in OBR-PD-82 List of devices.

Device name: Primodent  
Model/Type: Primodent, Type 1 (anterior)  
Primodent, Type 2 (posterior)  
Trend GD dent, Type 1 (anterior)  
Trend GD dent, Type 2 (posterior)  
Trend GD dent is alternative name for Primodent  
Available forms:  
Upper anterior: 41, 42, 43, 43A, 44, 45, 46, 01, 02, 03, 04, 05, 05A,  
06, 31, 32, 33, 34, 35, 36, 37, 37A, 38, 39, 32I, 34I, 37I,  
Lower anterior: I1, I2, I3, I4, I5, I6, I7, L2, L6, L8,  
Posterior teeth: T1 upper, T1 lower, T2 upper, T2 lower, T3 upper,  
T3 lower, T4 upper, T4 lower, T6 upper, T6 lower, S1 upper, S1  
lower, S3 upper, S3 lower, S5 upper, S5 lower  
Available Shades:  
Primodent:  
Y0-Y1-Y2-Y3-Y4-Y5-Y6,  
B1-B2-B3-B4-B5-B6,  
G1-G2-G3-G4-G5-G6  
Primodent-V:  
BL3,  
A1-A2-A3-A3,5-A4,  
B1-B2-B3-B4,  
C1-C2-C3-C4,  
D2-D3-D4  
All available combinations are listed in OBR-PD-83 List of devices.

Device name: Ref-Line  
Model/Type: Ref-Line, Type 1 (anterior)  
Ref-Line, Type 2 (posterior)  
ICX royal, Type 1 (anterior)

ICX royal, Type 2 (posterior)  
 ICX royal is alternative name for REF-LINE  
 Available forms:  
 Upper anterior: M1, M3, M4, M6, K3, K4, K6, N3, N4, N6, W3, W4,  
 W6, H3, H4, H6,  
 Lower anterior: V1, V3, V4, V6, V8, U3, U4, U6  
 Posterior teeth: R2 upper, R2 lower, R4 upper, R4 lower, R6 upper,  
 R6 lower,  
 Q1 upper, Q1 lower, Q3 upper, Q3 lower, Q5 upper, Q5 lower,  
 F2 upper, F2 lower, F4 upper, F4 lower, F6 upper, F6 lower.  
 Available Shades:  
 BL1-BL3,  
 A1-A2-A3-A3,5-A4,  
 B1-B2-B3-B4,  
 C1-C2-C3-C4,  
 D2-D3-D4  
 All available combinations are listed in OBR-PD-84 List of devices

Device: Materials for the preparation of custom-made dental devices –  
 other  
 EMDN: Q010699  
 Intended Purpose: K-30 S: Heat-curing acrylic resin for full and partial dentures by  
 using the packing/pressing technique  
 Polirepar S: Cold-curing acrylic resin for denture repairs  
 Polihot: Heat-curing acrylic resin for full and partial dentures  
 Policold: Cold-curing acrylic resin for dentures, repairs and  
 rebasing by using the cast technique  
 MDR code: MDN 1209  
 Classification: IIa  
 Basic UDI-DI: ++EPOLDBMJ2

Device name: K-30 S  
 Model/Type: K-30 S powder is available in various combinations of shade and  
 size of packaging.  
 Shades of powder: Pink, Pink veined, PN, PN veined, M26, M26V,  
 M41, M41V  
 Available package forms:  
 Powder – 350 g, 700 g, 1000 g  
 Liquid – 200 ml, 500 ml  
 All available variations are found in OBR-PD-75 List of devices K-  
 30 S and Polirepar S.

Device name: Polirepar S  
 Model/Type: Polirepar S powder is available in various combinations of shade  
 and size of packaging.  
 Shades of powder: Pink, Pink veined, PN, PNV, M26, M26V, M41,  
 M41V  
 Available package forms:  
 Powder – 200g, 1000 g  
 Liquid – 150 ml, 500 ml  
 available variations are found in OBR-PD-75 List of devices K-30 S  
 and Polirepar S.

Device name: Polihot  
Model/Type: Polihot powder is available in various combinations of shade and size of packaging.  
Shades of powder: Pink, Pink Veined, M26, M26 Veined,  
Available package forms:  
Powder – 700g, 1000 g,  
Liquid – 500 ml  
All available variations are found in OBR-PD-74 List of devices Polihot and Policold.

Device name: Policold  
Model/Type: Policold powder is available in various combinations of shade and size of packaging.  
Available shades of powder: Pink, Pink Veined, M26, M26 Veined  
Available package forms:  
Powder: 700 g, 1000 g  
Liquid: 500 ml  
Complete: 200 g powder + 150 ml liquid  
All available variations are found in OBR-PD-74 List of devices Polihot and Policold.

Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Intended Purpose: Cold-curing acrylic resin for temporary crowns and bridges.  
MDR code: MDN 1209  
Classification: IIa  
Basic UDI-DI: ++EPOLCBMHV

Device name: Politemp  
Model/Type: Politemp is available in various combinations of powder color and size of packaging.  
Shades of powder: A1, A2, A3, A3.5, B3, C2, D3, Incisal  
Available package forms:  
Powder – 80 g, 500 g  
Liquid – 150 ml, 500 ml  
All available variations are found in OBR-PD-76 List of devices Politemp.

Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Intended Purpose: Cold-curing acrylic resin for orthodontic appliances by using the spray-on technique  
MDR code: MDN 1209  
Classification: IIa  
Basic UDI-DI: ++EPOLORTOMHA

Device name: Ortopoli  
Model/Type: Ortopoli is available in various combinations of liquid color and size of packaging.

Shades of liquid: red, blue, yellow, colourless, fl. yellow, fl. orange,  
pink, green, indigo blue

Available package forms:

Powder – 350 g, 700 g, 1000 g

Liquid – 150 ml, 500 ml

All available variants are found in OBR-PD-77 List of devices  
Ortopoli.

Legislative act/requirements: Regulation (EU) 2017/745

Annex: IX

Date of issuing the list: 2026-06-24

Valid until: 2029-07-30

Detailed list of relevant common specifications and standards:

EU certificate No.: **MDR-0014**  
Issued to: POLIDENT d.o.o.  
Volčja Draga 42  
SRN of manufacturer: SI-MF-000000740  
Authorised representative: Not applicable  
SRN of authorised representative: Not applicable  
List of relevant common specifications and standards: ISO 13485:2016/A11:2021  
ISO 15223-1:2021  
ISO 14971:2019/ A11:2021  
ISO 20417:2021  
ISO 10993-1:2020  
ISO 10993-10:2010  
IEC 62366-1:2015/ A1:2020  
ISO 20795-1:2013  
ISO 20795-2:2013  
ISO 22112:2017  
ISO 10477:2020  
Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI: ++EPOLPMMACCJ5  
  
Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI: ++EPOLPMMACCTTT  
  
Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI: ++EPOLPMMACCTCBTP  
  
Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI: ++EPOLPINKCCJJ  
  
Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI code: ++EPOLPMMACCOS9E  
  
Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI: ++EPOLAPTKB

Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI: ++EPOLDBMJ2

Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI: ++EPOLCBMHV

Device: Materials for the preparation of custom-made dental devices – other  
EMDN: Q010699  
Basic UDI-DI: ++EPOLORTOMHA

Legislative  
act/requirements: Regulation (EU) 2017/745  
Annex: IX  
Date of issuing the list: 2026-06-24  
Valid until: 2029-07-30

For all further information we are available on telephone number 00 386 1 4778 159 and email: [mdr@siq.si](mailto:mdr@siq.si)

Management Systems Assessment  
MDR Product Manager  
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