

Mr.
 Dani Pečecnik
 POLIDENT d.o.o.
 Volčja Draga 42
 5293 Volčja Draga
 Slovenija

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 2025-05-16 and post audit report (OSV 00709/2025, 2025-05-29) the current edition MDR-0014/03 of the Certificate, Detailed list of product names, models and types and Detailed list of relevant common specifications and standards, MDR-0014/03 is cancelled and a new edition is issued:

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

Issued to:	POLIDENT d.o.o. Volčja Draga 42, Slovenija
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:	Ila
Device:	Materials for the preparation of custom-made dental devices – other
EMDN:	Q010699
Basic UDI-DI:	++EPOLAPTKB
Classification:	Ila
Device:	Materials for the preparation of custom-made dental devices – other
EMDN:	Q010699
Basic UDI-DI code:	++EPOLDBMJ2
Classification:	Ila
Device:	Materials for the preparation of custom-made dental devices – other
EMDN:	Q010699
Basic UDI-DI code:	++EPOLCBMHV
Classification:	Ila
Device:	Materials for the preparation of custom-made dental devices – other
EMDN:	Q010699
Basic UDI-DI code:	++EPOLORTOMHA
Classification:	Ila

Certification date: 2024-07-31
 Issue: 04/2025-06-10
 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 device 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 ZrO2 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
 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 geader*

* pink geader = 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:	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:	Ila
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
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, PN, PNV
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
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: ++EPOLOORTOMHA

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: 2025-06-10
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: ++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: 2025-06-10
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For all further information we are available on telephone number 00 386 1 4778 159 and email:
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