



SIQ Ljubljana | Mašera-Spasičeva ulica 10 | T +386 1 4778 100
SI-1000 Ljubljana | F +386 1 4778 444
Slovenija | info@siq.si, www.siq.si

vaš znak / your ref.: OSV/1081
naš znak / our ref.: 2026-03-25
datum / date:

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

Dear Mr. Dani Pečečnik!

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, due to the addition of new models, the current edition MDR-0014/04 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, 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: 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: 05/2026-03-25
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
 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

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: ++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: 2026-03-25

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: 2026-03-25
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

Management Systems Assessment
MDR Product Manager
Ana Pribaković Borštnik

