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vaš znak / your ref.:

OSV/1081

naš znak / our ref.:

datum / date:

2024-12-23

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

Dear Mr. Dani Pečičnik!

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 2024-11-15 and post audit report (OSV 01708/2024, 2024-12-23) the current edition MDR-0014/02 of the Certificate, Detailed list of product names, models and types and Detailed list of relevant common specifications and standards, MDR-0014/02 is cancelled and a new edition is issued:

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

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| Issued to:                        | POLIDENT d.o.o.<br>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: 03/2024-12-23  
 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  
 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  
 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  
 Shades: Basic: A1, A2, A3, A3.5, B1, B2, B3,

Clear\*,  
 Berry\*\*, Blue\*\*, Green\*\*, Orange\*\*,  
 Multilayer: BL3, A1, A2, A3, A3.5, B1, B3, D2  
 Thickness: Basic: 16, 20 mm  
 \* available also in 25 mm  
 \*\* only available in 20 mm  
 Multilayer: 15, 18, 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 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:  
pink, pink geadert\*  
\* pink geadert = pink veined  
Thickness:  
20, 25, 27, 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: IIa  
Basic UDI-DI: ++EPOLAPTKB  
Place of production: RAPE 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  
rebasings 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: 2024-12-23

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: 2024-12-23  
Valid until: 2029-07-30

For all further information we are available on telephone number 00 386 1 4778 159 and email:  
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Management Systems Assessment  
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