

# Declaration of Conformity



**Directive application:** 93/42/EC amended by 2007/47/EC  
**Route to the compliance:** Annex II excluding sec.4  
**Conformity Declaration by the standard:** ISO 13485:2016

**Manufacturer:** Unión Dental, S.A.  
**Address:** PS Estación, 4. 28550-Tielmes, MADRID, SPAIN

**Notified Body number:** 1639  
**Notified Body:** SGS Belgium N.V. Noorderlaan 87, BE-2030. Antwerpen, Belgium

**Notified Body certificate number:** ES19/86895  
**With extended validity period:** from April 17, 2023 until December 31, 2028  
**(In accordance of article 120 of MDR 745/2017 amended by Regulation (UE) 607/2023)**

**Product type:** Dental polymer resin blank  
**Destined use by the manufacturer:** For dental structures, crowns and bridges  
**Classification:** Class IIa (Directive 93/42/EEC, rule 5)  
Invasive devices of the oral cavity and for long-term use

**Product:** ANAXDENT PMMA  
**Type:** Discs for milling Cad/Cam with different shades, measures & chromatic layers

**References included:** See annex ANA2025-1

**Standards used:**

- ISO 13485:2016 - Medical Devices -- Quality management systems -- Requirements for regulatory purposes
- EN 1641:2009 - Dentistry. Medical devices for dentistry. Materials
- EN ISO 10477:2020 – Dentistry. Polymer-based crown and veneering materials
- EN ISO 20795-1:2013 – Dentistry. Base polymers. Part. 1 – Denture base polymers
- EN ISO 7405:2018 – Dentistry. Evaluation of biocompatibility of medical devices in dentistry
- EN ISO 10993-1:2021- Biolog. evaluation medical devices. Part 1, Ev. & testing whitening a risk management process
- EN ISO 10993-5:2009- Biological evaluation of medical devices. Part 5, Tests for In vitro cytotoxicity
- EN ISO 14971:2020 –Medical devices - Application of risk management to medical devices
- EN ISO 19011:2018 - Guidelines for auditing management systems
- EN ISO 15223-1:2022 – Medical Devices. Symbols to be used with medical devices labels, labelling and information to be supplied. Part 1 General requirements.

The hereby undersigned certifies that the sanitary products aforementioned satisfy all the above mentioned Directive's essential requirements. Therefore, the absence of any health and safe compromise for people is guaranteed, as long as the products were used according to their foreseen finality. Also the hereby undersigned declares that there have been no significant changes (according to MDCG 2020-3) in the design or purpose of use of the products after the date of application of MDR 2017/745 (05/26/2021).

Place: Madrid. SPAIN

Date: 27.02.2025

The manufacturer: **Unión Dental, S.A.**  
PS Estación, 4. 28550-MADRID

Unión Dental S.A.  
EUDAMED Actor identification  
SRN:ES-MF-000003189





# Declaration of Conformity

Product: **ANAXDENT PMMA** Type: *Discs for milling Cad/Cam*

References included (Page 1 of 4)

Reference	Description	UDI-DI
18162120	ANAXDENT The Show U 10 - Layer PMMA, color A1, measures 98,5 / 20mm	08435288491004
18132220	ANAXDENT The Show U 10 - Layer PMMA, color A2, measures 98,5 / 20mm	08435288491011
18132320	ANAXDENT The Show U 10 - Layer PMMA, color A3, measures 98,5 / 20mm	08435288491028
18132520	ANAXDENT The Show U 10 - Layer PMMA, color A3,5, measures 98,5 / 20mm	08435288491035
18132420	ANAXDENT The Show U 10 - Layer PMMA, color A4, measures 98,5 / 20mm	08435288491042
18131020	ANAXDENT The Show U 10 - Layer PMMA, color B0, measures 98,5 / 20mm	08435288491059
18133120	ANAXDENT The Show U 10 - Layer PMMA, color B1, measures 98,5 / 20mm	08435288491066
18133220	ANAXDENT The Show U 10 - Layer PMMA, color B2, measures 98,5 / 20mm	08435288491073
18133520	ANAXDENT The Show U 10 - Layer PMMA, color B3, measures 98,5 / 20mm	08435288491080
18133420	ANAXDENT The Show U 10 - Layer PMMA, color B4, measures 98,5 / 20mm	08435288491097
18131120	ANAXDENT The Show U 10 - Layer PMMA, color BL1, measures 98,5 / 20mm	08435288496160
18131220	ANAXDENT The Show U 10 - Layer PMMA, color BL2, measures 98,5 / 20mm	08435288496153
18131320	ANAXDENT The Show U 10 - Layer PMMA, color BL3, measures 98,5 / 20mm	08435288496146
18141420	ANAXDENT The Show U 10 - Layer PMMA, color BL4, measures 98,5 / 20mm	08435288496139
18134120	ANAXDENT The Show U 10 - Layer PMMA, color C1, measures 98,5 / 20mm	08435288491103
18134220	ANAXDENT The Show U 10 - Layer PMMA, color C2, measures 98,5 / 20mm	08435288491110
18134320	ANAXDENT The Show U 10 - Layer PMMA, color C3, measures 98,5 / 20mm	08435288491127
18134420	ANAXDENT The Show U 10 - Layer PMMA, color C4, measures 98,5 / 20mm	08435288491134
18135220	ANAXDENT The Show U 10 - Layer PMMA, color D2, measures 98,5 / 20mm	08435288491141
18135320	ANAXDENT The Show U 10 - Layer PMMA, color D3, measures 98,5 / 20mm	08435288491158
18142120	ANAXDENT The Show Z 10 - Layer PMMA, color A1, measures 95 / 20mm	08435288496009
18142220	ANAXDENT The Show Z 10 - Layer PMMA, color A2, measures 95 / 20mm	08435288496016
18142320	ANAXDENT The Show Z 10 - Layer PMMA, color A3, measures 95 / 20mm	08435288496023
18142520	ANAXDENT The Show Z 10 - Layer PMMA, color A3,5, measures 95 / 20mm	08435288496030
18142420	ANAXDENT The Show Z 10 - Layer PMMA, color A4, measures 95 / 20mm	08435288496047
18143020	ANAXDENT The Show Z 10 - Layer PMMA, color B0, measures 95 / 20mm	08435288495996
18143120	ANAXDENT The Show Z 10 - Layer PMMA, color B1, measures 95 / 20mm	08435288496054
18143220	ANAXDENT The Show Z 10 - Layer PMMA, color B2, measures 95 / 20mm	08435288496061
18143320	ANAXDENT The Show Z 10 - Layer PMMA, color B3, measures 95 / 20mm	08435288496078
18143420	ANAXDENT The Show Z 10 - Layer PMMA, color B4, measures 95 / 20mm	08435288496085
18141120	ANAXDENT The Show Z 10 - Layer PMMA, color BL1, measures 95 / 20mm	08435288496177
18141220	ANAXDENT The Show Z 10 - Layer PMMA, color BL2, measures 95 / 20mm	08435288495989
18141320	ANAXDENT The Show Z 10 - Layer PMMA, color BL3, measures 95 / 20mm	08435288496191
18144120	ANAXDENT The Show Z 10 - Layer PMMA, color BL4, measures 95 / 20mm	08435288496184
18144120	ANAXDENT The Show Z 10 - Layer PMMA, color BL4, measures 95 / 20mm	08435288496092
18144220	ANAXDENT The Show Z 10 - Layer PMMA, color C2, measures 95 / 20mm	08435288496108
18144320	ANAXDENT The Show Z 10 - Layer PMMA, color C3, measures 95 / 20mm	08435288496115
18144420	ANAXDENT The Show Z 10 - Layer PMMA, color C4, measures 95 / 20mm	08435288496122
18132125	ANAXDENT The Show U 10 - Layer PMMA, color A1, measures 98,5 / 25mm	08435288496627
18132225	ANAXDENT The Show U 10 - Layer PMMA, color A2, measures 98,5 / 25mm	08435288496634
18132325	ANAXDENT The Show U 10 - Layer PMMA, color A3, measures 98,5 / 25mm	08435288496641
18132525	ANAXDENT The Show U 10 - Layer PMMA, color A3,5, measures 98,5 / 25mm	08435288496658



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Product: **ANAXDENT PMMA** Type: Discs for milling Cad/Cam

## References included (Page 2 of 4)

Reference	Description	UDI-DI
18133125	ANAXDENT The Show U 10 - Layer PMMA, color B1, measures 98,5 / 25mm	08435288496689
18133225	ANAXDENT The Show U 10 - Layer PMMA, color B2, measures 98,5 / 25mm	08435288496696
18131125	ANAXDENT The Show U 10 - Layer PMMA, color BL1, measures 98,5 / 25mm	08435288496962
18131325	ANAXDENT The Show U 10 - Layer PMMA, color BL3, measures 98,5 / 25mm	08435288496986
18141425	ANAXDENT The Show U 10 - Layer PMMA, color BL4, measures 98,5 / 25mm	08435288496788
18134125	ANAXDENT The Show U 10 - Layer PMMA, color C1, measures 98,5 / 25mm	08435288496726
18135225	ANAXDENT The Show U 10 - Layer PMMA, color D2, measures 98,5 / 25mm	08435288496764
18135325	ANAXDENT The Show U 10 - Layer PMMA, color D3, measures 98,5 / 25mm	08435288496771
18142125	ANAXDENT The Show Z 10 - Layer PMMA, color A1, measures 95 / 25mm	08435288496795
18142225	ANAXDENT The Show Z 10 - Layer PMMA, color A2, measures 95 / 25mm	08435288496801
18142325	ANAXDENT The Show Z 10 - Layer PMMA, color A3, measures 95 / 25mm	08435288496818
18142525	ANAXDENT The Show Z 10 - Layer PMMA, color A3,5, measures 95 / 25mm	08435288496825
18143025	ANAXDENT The Show Z 10 - Layer PMMA, color B0, measures 95 / 25mm	08435288496849
18143125	ANAXDENT The Show Z 10 - Layer PMMA, color B1, measures 95 / 25mm	08435288496856
18141125	ANAXDENT The Show Z 10 - Layer PMMA, color BL1, measures 95 / 25mm	08435288497006
18141225	ANAXDENT The Show Z 10 - Layer PMMA, color BL2, measures 95 / 25mm	08435288497013
18141325	ANAXDENT The Show Z 10 - Layer PMMA, color BL3, measures 95 / 25mm	08435288497020
18141425	ANAXDENT The Show U 10 - Layer PMMA, color BL4, measures 98,5 / 25mm	08435288497037
18144125	ANAXDENT The Show Z 10 - Layer PMMA, color C1, measures 95 / 25mm	08435288497044
18132130	ANAXDENT The Show U 10 - Layer PMMA, color A1, measures 98,5 / 30mm	08435288493008
18132230	ANAXDENT The Show U 10 - Layer PMMA, color A2, measures 98,5 / 30mm	08435288493015
18132330	ANAXDENT The Show U 10 - Layer PMMA, color A3, measures 98,5 / 30mm	08435288493022
18132530	ANAXDENT The Show U 10 - Layer PMMA, color A3,5, measures 98,5 / 30mm	08435288493039
18133130	ANAXDENT The Show U 10 - Layer PMMA, color B1, measures 98,5 / 30mm	08435288493060
18131130	ANAXDENT The Show U 10 - Layer PMMA, color BL1, measures 98,5 / 30mm	08435288493176
18141430	ANAXDENT The Show U 10 - Layer PMMA, color BL4, measures 98,5 / 30mm	08435288493206
18134130	ANAXDENT The Show U 10 - Layer PMMA, color C1, measures 98,5 / 30mm	08435288493107
18142130	ANAXDENT The Show Z 10 - Layer PMMA, color A1, measures 95 / 30mm	08435288493213
18142230	ANAXDENT The Show Z 10 - Layer PMMA, color A2, measures 95 / 30mm	08435288493220
18142330	ANAXDENT The Show Z 10 - Layer PMMA, color A3, measures 95 / 30mm	08435288493237
18142530	ANAXDENT The Show Z 10 - Layer PMMA, color A3,5, measures 95 / 30mm	08435288493244
18143030	ANAXDENT The Show Z 10 - Layer PMMA, color B0, measures 95 / 30mm	08435288493268
18143130	ANAXDENT The Show Z 10 - Layer PMMA, color B1, measures 95 / 30mm	08435288493275
18141330	ANAXDENT The Show Z 10 - Layer PMMA, color BL3, measures 95 / 30mm	08435288493411
18917025	ANAXDENT The Preview U Monolayer PMMA, color A1, measures 98,5 / 25mm	08435288493848
18914025	ANAXDENT The Preview U Monolayer PMMA, color A2, measures 98,5 / 25mm	08435288493855
18916025	ANAXDENT The Preview U Monolayer PMMA, color A3, measures 98,5 / 25mm	08435288493862
18911025	ANAXDENT The Preview U Monolayer PMMA, color B1, measures 98,5 / 25mm	08435288493893
18913025	ANAXDENT The Preview U Monolayer PMMA, color BL1, measures 98,5 / 25mm	08435288494005
18912025	ANAXDENT The Preview U Monolayer PMMA, color BL3, measures 98,5 / 25mm	08435288494029
18915025	ANAXDENT The Preview U Monolayer PMMA, color BL4, measures 98,5 / 25mm	08435288494036



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Product: **ANAXDENT PMMA** Type: *Discs for milling Cad/Cam*

References included (Page 3 of 4)

Reference	Description	UDI-DI
18890025	ANAXDENT The Preview Z Monolayer PMMA, color A1, measures 95 / 25mm	08435288494043
18880025	ANAXDENT The Preview Z Monolayer PMMA, color A2, measures 95 / 25mm	08435288494050
18870025	ANAXDENT The Preview Z Monolayer PMMA, color B1, measures 95 / 25mm	08435288494098
18890225	ANAXDENT The Preview Z Monolayer PMMA, color BL1, measures 95 / 25mm	08435288495033
18860025	ANAXDENT The Preview Z Monolayer PMMA, color BL2, measures 95 / 25mm	08435288495040
18890125	ANAXDENT The Preview Z Monolayer PMMA, color BL3, measures 95 / 25mm	08435288495057
18930020	ANAXDENT The Preview U Monolayer PMMA, color A1, measures 98,5 / 20mm	08435288493435
18950020	ANAXDENT The Preview U Monolayer PMMA, color A2, measures 98,5 / 20mm	08435288493442
18910020	ANAXDENT The Preview U Monolayer PMMA, color A3, measures 98,5 / 20mm	08435288493459
18920020	ANAXDENT The Preview U Monolayer PMMA, color B1, measures 98,5 / 20mm	08435288493480
18960020	ANAXDENT The Preview U Monolayer PMMA, color BL1, measures 98,5 / 20mm	08435288493602
18970020	ANAXDENT The Preview U Monolayer PMMA, color BL3, measures 98,5 / 20mm	08435288493626
18940020	ANAXDENT The Preview U Monolayer PMMA, color BL4, measures 98,5 / 20mm	08435288493633
18100020	ANAXDENT The Guide U CLEAR BLANK, measures 98,5 / 20mm	08435288492582
18190100	ANAXDENT The Guide SCAN U PMMA Blank x-ray, measures 98,5 / 20mm	08435288499703
18820020	ANAXDENT The Preview Z Monolayer PMMA, color A1, measures 95 / 20mm	08435288493640
18840020	ANAXDENT The Preview Z Monolayer PMMA, color A2, measures 95 / 20mm	08435288493657
18830020	ANAXDENT The Preview Z Monolayer PMMA, color B1, measures 95 / 20mm	08435288493695
18810020	ANAXDENT The Preview Z Monolayer PMMA, color BL1, measures 95 / 20mm	08435288493800
18850020	ANAXDENT The Preview Z Monolayer PMMA, color BL3, measures 95 / 20mm	08435288493824
18300020	ANAXDENT The Guide Z CLEAR BLANK, measures 95 / 20mm	08435288492841
18100030	ANAXDENT The Guide U CLEAR BLANK, measures 98,5 / 16mm	08435288493299
18300030	ANAXDENT The Guide Z CLEAR BLANK, measures 95 / 16mm	08435288493503
18121112	ANAXDENT U PMMA MULTI BLANK, color A1, measures 98,5 / 12mm	08435288494203
18121212	ANAXDENT U PMMA MULTI BLANK, color A2, measures 98,5 / 12mm	08435288494210
18121312	ANAXDENT U PMMA MULTI BLANK, color A3, measures 98,5 / 12mm	08435288494227
18121412	ANAXDENT U PMMA MULTI BLANK, color A3,5, measures 98,5 / 12mm	08435288494234
18121012	ANAXDENT U PMMA MULTI BLANK, color B0, measures 98,5 / 12mm	08435288494258
18122112	ANAXDENT U PMMA MULTI BLANK, color B1, measures 98,5 / 12mm	08435288494265
18122212	ANAXDENT U PMMA MULTI BLANK, color B2, measures 98,5 / 12mm	08435288494272
18321112	ANAXDENT Z PMMA MULTI BLANK, color A1, measures 95 / 12mm	08435288494289
18321212	ANAXDENT Z PMMA MULTI BLANK, color A2, measures 95 / 12mm	08435288494296
18321312	ANAXDENT Z PMMA MULTI BLANK, color A3, measures 95 / 12mm	08435288494302
18321412	ANAXDENT Z PMMA MULTI BLANK, color A3,5, measures 95 / 12mm	08435288494319
18321012	ANAXDENT Z PMMA MULTI BLANK, color B0, measures 95 / 12mm	08435288494333
18322112	ANAXDENT Z PMMA MULTI BLANK, color B1, measures 95 / 12mm	08435288494340
18322212	ANAXDENT Z PMMA MULTI BLANK, color B2, measures 95 / 12mm	08435288494357
18121120	ANAXDENT U PMMA MULTI BLANK, color A1, measures 98,5 / 20mm	08435288495002
18121220	ANAXDENT U PMMA MULTI BLANK, color A2, measures 98,5 / 20mm	08435288495019
18121320	ANAXDENT U PMMA MULTI BLANK, color A3, measures 98,5 / 20mm	08435288495026
18121420	ANAXDENT U PMMA MULTI BLANK, color A3,5, measures 98,5 / 20mm	08435288495132





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Product: **ANAXDENT PMMA** Type: Discs for milling Cad/Cam

References included (Page 4 of 4)

Reference	Description	UDI-DI
18120220	ANAXDENT U PMMA MULTI BLANK, color B0, measures 98,5 / 20mm	08435288495071
18122120	ANAXDENT U PMMA MULTI BLANK, color B1, measures 98,5 / 20mm	08435288495217
18122220	ANAXDENT U PMMA MULTI BLANK, color B2, measures 98,5 / 20mm	08435288495224
18122820	ANAXDENT U PMMA MULTI BLANK, color D2, measures 98,5 / 20mm	08435288495194
18122920	ANAXDENT U PMMA MULTI BLANK, color D3, measures 98,5 / 20mm	08435288495200
18221120	ANAXDENT AG PMMA MULTI BLANK, color A1, measures 101 / 20mm	08435288495088
18221220	ANAXDENT AG PMMA MULTI BLANK, color A2, measures 101 / 20mm	08435288495095
18221320	ANAXDENT AG PMMA MULTI BLANK, color A3, measures 101 / 20mm	08435288495101
18220220	ANAXDENT AG PMMA MULTI BLANK, color B0, measures 101 / 20mm	08435288495156
18222120	ANAXDENT AG PMMA MULTI BLANK, color B1, measures 101 / 20mm	08435288495798
18222220	ANAXDENT AG PMMA MULTI BLANK, color B2, measures 101 / 20mm	08435288495804
18321120	ANAXDENT Z PMMA MULTI BLANK, color A1, measures 95 / 20mm	08435288495163
18321220	ANAXDENT Z PMMA MULTI BLANK, color A2, measures 95 / 20mm	08435288495170
18321320	ANAXDENT Z PMMA MULTI BLANK, color A3, measures 95 / 20mm	08435288495187
18321420	ANAXDENT Z PMMA MULTI BLANK, color A3,5, measures 95 / 20mm	08435288495385
18320220	ANAXDENT Z PMMA MULTI BLANK, color B0, measures 95 / 20mm	08435288495231
18322120	ANAXDENT Z PMMA MULTI BLANK, color B1, measures 95 / 20mm	08435288495408
18322220	ANAXDENT Z PMMA MULTI BLANK, color B2, measures 95 / 20mm	08435288495415
18121116	ANAXDENT U PMMA MULTI BLANK, color A1, measures 98,5 / 16mm	08435288495248
18121216	ANAXDENT U PMMA MULTI BLANK, color A2, measures 98,5 / 16mm	08435288495255
18121316	ANAXDENT U PMMA MULTI BLANK, color A3, measures 98,5 / 16mm	08435288495262
18121416	ANAXDENT U PMMA MULTI BLANK, color A3,5, measures 98,5 / 16mm	08435288495491
18120216	ANAXDENT U PMMA MULTI BLANK, color B0, measures 98,5 / 16mm	08435288495316
18122116	ANAXDENT U PMMA MULTI BLANK, color B1, measures 98,5 / 16mm	08435288495514
18122216	ANAXDENT U PMMA MULTI BLANK, color B2, measures 98,5 / 16mm	08435288495521
18321116	ANAXDENT Z PMMA MULTI BLANK, color A1, measures 95 / 16mm	08435288495606
18321216	ANAXDENT Z PMMA MULTI BLANK, color A2, measures 95 / 16mm	08435288495613
18321316	ANAXDENT Z PMMA MULTI BLANK, color A3, measures 95 / 16mm	08435288495620
18321416	ANAXDENT Z PMMA MULTI BLANK, color A3,5, measures 95 / 16mm	08435288495637
18320216	ANAXDENT Z PMMA MULTI BLANK, color B0, measures 95 / 16mm	08435288495651
18322116	ANAXDENT Z PMMA MULTI BLANK, color B1, measures 95 / 16mm	08435288495668
18322216	ANAXDENT Z PMMA MULTI BLANK, color B2, measures 95 / 16mm	08435288495675
18121125	ANAXDENT U PMMA MULTI BLANK, color A1, measures 98,5 / 25mm	08435288496207
18121225	ANAXDENT U PMMA MULTI BLANK, color A2, measures 98,5 / 25mm	08435288496214
18121325	ANAXDENT U PMMA MULTI BLANK, color A3, measures 98,5 / 25mm	08435288496221

The manufacturer: **Unión Dental, S.A.**

PS Estación, 4. 28550-MADRID

Date: 27.02.2025

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EUDAMED Actor identification  
SRN:ES-MF-000003189

