EC Declaration of Conformity

Established in accordance with the Medical Device Regulation 93/42/AT and the Medical Device Directive 93/42/EEC

Manufacturer:	**IMICRYL DİŞ MALZEMELERİ SANAYİ ve TİCARET ANONİM ŞİRKETİ FETİH MAHALLESİ MAHİR SOKAK NO: 5/201 42030 KARATAY/KONYA**
Product name:	Dental Prosthesis Materials
GMDN CODE:	38643 – 38644 – 16727 – 34811 – 16187
Brand:	Indicated in Annex–1
Product Description:	Used in the dental industry; artificial teeth to denture base materials, polymethylmethacrylate–based polymer, methacrylate–based monomer denture base repair and porcelain powder and liquid materials.
Applied Directives:	MD Regulation 93/42/AT on Medical Devices, conformity assessment according to Annex V. Class IIA according to Directive 93/42/ECC Annex IX, Rule 8, 2nd indent)
Applied Standarts	Indicated in Annex–2

"MANUFACTURER" here with declares that the above–mentioned product(s) meet all applicable provisions of the Medical Device Directive 93/42/EEC Class IIA (non–sterile). The products is safe under prescribed and reasonably foreseeable conditions of storage and use.

"MANUFACTURER" has implemented measures assuring that all products of the above mentioned type are safe and fulfill essential requirements of the 93/42/EEC Medical Device Directive.

"MANUFACTURER" has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post–production phase and to implement appropriate means for any necessary corrective actions.

"MANUFACTURER" has hereby declare that our products that we produce don't contain any drugs.

"MANUFACTURER" has hereby declare that We don't produce our products from Human Blood Derrvatives and animal tissue.

Certificate No:	1783-MDD-191
Certificate Issue Date:	24.06.2020
Certificate Validity Date:	26.05.2024
Notified Body Identification No:	1783
Notified Body Name:	TÜRK STANDARDLARI ENSTİTÜSÜ
Adress:	Necatibey Caddesi No: 112 06100 Bakanlıklar/ANKARA/TURKEY

IMICRYL® DİŞ MALZEMELERİ SAN. ve TİC. A.Ş.

Annex 1: Brands

Annex 2: Applied Standarts

Abdullah YALÇINKAYA / Product Manager

on Behalf of "MANUFACTURER", KONYA

Annex 1: Brands

Acrylic Teeth: Imident Lux, Primadent Plus, Selcuk, Pama, Primadent (GMDN:38643)
Isosit and Composite Teeth: Pama, Primadent Plus (GMDN:38643)
Dental Acrylic Powders: IQ-15, SC, Imident, Imibase, O-80 (GMDN:16727)
Dental Acrylic Liquids: IQ-15, SC, Imident, Imibase, O-80 (GMDN:34811)
Porcelain Powders and Liquids: Ceramica (GMDN:16187)

Annex 2: Prosthesis Material Applicable Standards and Directives

No	Standard or Directive Name
1	93/42/EEC Medical Device Directive
2	Regulation of Medical Devices Number: 27957 (07.06.2011)
3	Meddev 2.1/1 Definitions of “medical devices”, “accessory” and “manufacturer” (April 1994)
4	Meddev 2.4/1 Rev 09 Classification of Medical Devices (June 2010)
5	Meddev 2.5/10 Guideline for Authorised Representatives (January 2012)
6	Meddev 2.7/1 Rev 04 Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93.42.EEC and 90.385.EEC (June 2016)
7	Meddev 2.7/2 Rev 02 Guidelines for Competent Authorities for Making a Validation / Assessment of a Clinical Investigation Application Under Directives 90/385/EEC and 93/42/EC (September 2015)
8	Meddev 2.7/3 Rev 03 Clinical investigations: Serious Adverse Reporting Under Directives 90/385/EEC and 93/42/EC (May 2015)
9	Meddev 2.7/4 Guidelines on Clinical Investigations: A Guide for Manufacturers and Notified Bodies (December 2010)
10	Meddev 2.12/1 Rev 08 Guidelines On a Medical Devices Vigilance System (January 2013)
11	Meddev 2.12/2 Rev 02 Post Market Clinical Follow–up Studies (January 2012)
12	EN ISO 13485:2016 Medical devices–Quality management systems–Requirements for regulatory purposes
13	EN ISO 13485/AC:2017 Medical devices–Quality management systems–Requirements for regulatory purposes
14	EN ISO 14971:2012 Application of risk management to medical devices
15	EN ISO 15223–1:2016 Medical devices–Symbols to be used with medical device labels, labelling and information to be supplied
16	TS EN 1041+A1:2014 Information supplied by the manufacturer of medical devices
17	EN ISO 10993–1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
18	EN ISO 10993–5:2010 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
19	EN ISO 10993–10:2014 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
20	EN ISO 7405:2008 – Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
21	ASTM F 1980–16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (2016)
22	TS EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
23	TS EN ISO/IEC 17050-1:2007 Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements
24	TS EN ISO/IEC 17050-2:2004 Conformity Assessment - Supplier's Declaration Of Conformity - Part 2: Supporting Documentation
25	“European Commission ‘The ‘Blue Guide’ on the implementation of EU product rules”
26	EN ISO 22112:2017 Dentistry–Artificial teeth for dental prostheses
27	EN ISO 20795–1:2013 Dentistry–Base polymers–Part 1: Denture base polymers

No	Standard or Directive Name
28	EN ISO 6872:2015 Dentistry–Ceramic Materials
29	TS EN ISO 7491: 2000 Dental materials- Determination of colour stability
30	TS EN ISO 9693-1: 2012 Dentistry - Compatibility testing - Part 1: Metal-ceramic systems
31	TS EN ISO 9693-2 Dentistry - Compatibility testing - Part 2: Ceramic-ceramic systems

EC Declaration of Conformity

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Manufacturer:	**IMICRYL DİŞ MALZEMELERİ SANAYİ ve TİCARET ANONİM ŞİRKETİ FETİH MAHALLESI MAHİR SOKAK NO: 5/201 42030 KARATAY/KONYA**
Product name:	Dental Restorative Materials
GMDN CODE:	16705-16710-62200-36153-16704-38649-34782-36095
Brand:	Indicated in Annex–1 and Annex-2
Product Description:	Product is filling and root canal fillingmaterials, is used in the repair of permanent teeth (or primary teeth) caries and in the treatment.Designed to be used in dentistry for the treatment.
Applied Directives:	MD Directive 93/42/ECC on Medical Devices, conformity assessment according to Annex V. Class IIA according to Directive 93/42/ECC Annex IX, Rule 8, 2nd indent)
Applied Standarts	Indicated in Annex–3

"MANUFACTURER" here with declares that the above–mentioned product(s) meet all applicable provisions of the EC MD Directive 93/42/EEC Class IIA (non–sterile). The products is safe under prescribed and reasonably foreseeable conditions of storage and use.

"MANUFACTURER" has implemented measures assuring that all products of the above mentioned type are safe and fulfill essential requirements of the 93/42/EEC Directive.

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IMICRYL DİŞ MALZEMELERİ SAN. ve TİC. A.Ş.

Annex 1: Brands

Annex 2: Applied Standarts

Abdullah YALÇINKAYA / Product Manager

on Behalf of "MANUFACTURER", KONYA

Annex 1: Brands of Restorative Materials

Dental Filling Materials

Imibond P, Imibond Aqua P (GMDN CODE:16705)

Imibond F (GMDN CODE:16710)

Zino-EG (GMDN CODE:62200)

Dental Restorative Filling Materials

Nova Etch, Royalry, Panora 200 (GMDN CODE:36153)

Nova Glass F, Nova Glass L, Imibond-G, Nova Glass L+, Nova Glass LC, Nova Glass BF, Nova Glass GL, Nova Aqua GIL, Nova Aqua GIF, Mesawell, Nova Resin (GMDN CODE: 16704)

Nova, Nova Compomer Flow (GMDN CODE: 38649)

Dental Restorative Composite Materials

Nova C, Elixa, Nova Compo HS, Nova Compo HF, Nova Compo SF, Nova Compo Bulkfill, Nova Compo MHC (GMDN CODE: 38649)

Dental Restorative Adhesive Bonding

Nova Compo B, Nova B, Elixa, R&D Series Nova Compo B Plus, Nova Compo-B Plus (GMDN CODE: 34782)

Dental Canal Filling Materials

Cavitimi, Calciplus, Therra, Calciplus RL, Calciplus LC, Calciplus BX, Imical, Biofactor, Bioforce (GMDN CODE:36095)

Annex 2: Restorative Materials Applicable Standards and Directives

No	Standard or Directive Name
1	93/42/EEC Medical Device Directive
2	Regulation of Medical Devices Number: 27957 (07.06.2011)
3	Meddev 2.1/1 Definitions of “medical devices”, “accessory” and “manufacturer” (April 1994)
4	Meddev 2.4/1 Rev 09 Classification of Medical Devices (June 2010)
5	Meddev 2.5/10 Guideline for Authorised Representatives (January 2012)
6	Meddev 2.7/1 Rev 04 Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93.42.EEC and 90.385.EEC (June 2016)
7	Meddev 2.7/2 Rev 02 Guidelines for Competent Authorities for Making a Validation / Assessment of a Clinical Investigation Application Under Directives 90/385/EEC and 93/42/EC (September 2015)
8	Meddev 2.7/3 Rev 03 Clinical investigations: Serious Adverse Reporting Under Directives 90/385/EEC and 93/42/EC (May 2015)
9	Meddev 2.7/4 Guidelines on Clinical Investigations: A Guide for Manufacturers and Notified Bodies (December 2010)
10	Meddev 2.12/1 Rev 08 Guidelines On a Medical Devices Vigilance System (January 2013)
11	Meddev 2.12/2 Rev 02 Post Market Clinical Follow–up Studies (January 2012)
12	EN ISO 13485:2016 Medical devices–Quality management systems–Requirements for regulatory purposes
13	EN ISO 13485/AC:2017 Medical devices–Quality management systems–Requirements for regulatory purposes
14	EN ISO 14971:2012 Application of risk management to medical devices

No	Standard or Directive Name
15	EN ISO 15223–1:2016 Medical devices–Symbols to be used with medical device labels, labelling and information to be supplied
16	TS EN 1041+A1:2014 Information supplied by the manufacturer of medical devices
17	EN ISO 10993–1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
18	EN ISO 10993–5:2010 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
19	EN ISO 10993–10:2014 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
20	EN ISO 7405:2008 – Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
21	ASTM F 1980–16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (2016)
22	TS EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
23	TS EN ISO/IEC 17050-1:2007 Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements
24	TS EN ISO/IEC 17050-2:2004 Conformity Assessment - Supplier's Declaration Of Conformity - Part 2: Supporting Documentation
25	“European Commission ‘The ‘Blue Guide’ on the implementation of EU product rules”
26	EN ISO 9917–1:2007 Water–Based Cement Part 1 powder/ liquid acid–base cement
27	EN ISO 9917–2:2017 Dentistry – Water–based cements – Part 2: Resin–modified cements
28	EN ISO 3107:2011 Dentistry–Zinc oxide/eugenol cements and zinc oxide/non–eugenol cements
29	EN ISO 6876:2012 Dental root canal sealing materials
30	EN ISO 4049:2009 Polymer–based restorative materials
31	EN ISO 29022:2013 Dentistry – Adhesion – Notched–edge shear bond strength test

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Manufacturer: **IMICRYL DİŞ MALZEMELERİ SANAYİ ve TİCARET ANONİM ŞİRKETİ FETİH MAHALLESİ MAHİR SOKAK NO: 5/201 42030 KARATAY/KONYA**

Product name: Dental Protective Materials

GMDN CODE: 34771–35698–42345

Brand: Indicated in Annex–1

Product Description: Product; In dentistry, used in the protective material for preventing of tooth loss. Used in pre–treatment for irrigation and cleaning materials.

Applied Directives: Medical Devices Directive 93/42/EEC, Class IIa according to Annex IX Rule 8 for Fissure Sealent and Fluorine Varnish products, Class IIa (Non-steril) according to Annex IX Rule 6 for Canal Irrigation and Cleaning Solutions Annex – V

Applied Standarts Indicated in Annex–2

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Abdullah YALÇINKAYA / Product Manager

on Behalf of "MANUFACTURER", KONYA

Annex 1: Brands

Annex 2: Applied Standarts

Annex 1: Brands of Protective Materials

E.D.T.A, PROSIMI, VAYFIC, PAMA (GMDN: 42345)

FISSURED NOVA, FISSURED NOVA PLUS (GMDN: 34771)

POLIMO VARNISH (GMDN:35698)

Annex 2: Protective Material Applicable Standards and Directives

No	Standard or Directive Name
1	93/42/EEC Medical Device Directive
2	Regulation of Medical Devices Number: 27957 (07.06.2011))
3	Meddev 2.1/1 Definitions of “medical devices”, “accessory” and “manufacturer” (April 1994)
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5	Meddev 2.5/10 Guideline for Authorised Representatives (January 2012)
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7	Meddev 2.7/2 Rev 02 Guidelines for Competent Authorities for Making a Validation / Assessment of a Clinical Investigation Application Under Directives 90/385/EEC and 93/42/EC (September 2015)
8	Meddev 2.7/3 Rev 03 Clinical investigations: Serious Adverse Reporting Under Directives 90/385/EEC and 93/42/EC (May 2015)
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24	TS EN ISO/IEC 17050-2:2004 Conformity Assessment - Supplier's Declaration Of Conformity - Part 2: Supporting Documentation
25	“European Commission ‘The ‘Blue Guide’ on the implementation of EU product rules”
26	EN ISO 6874:2015 Dentistry – Polymer–based pit and fissure sealants
27	EN ISO 17730:2014 Dentistry – Fluoride varnishes