EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60144732 0001

Report No.: 12031520 002

Manufacturer:
HDI Inc.
A-1504, 14, Sagimakgol-ro 45beon-gil
Jungwon-gu, Seongnam-si
Gyeonggi-do 13209
Republic of Korea

Products: Dental etchant and Dental composite resin

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-09

Date: 2019-12-09

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Romanenco Alexandru
Date: 2024.10.17 10:23:08 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

EC DECLARATION OF CONFORMITY

Manufacturer :	*HDI Inc.* *A-504, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13209 Republic of Korea* *SRN_KR-MF-000026600*
EU Representative :	*KTR Europe GmbH* *Mergenthalerallee 77, Eschborn, Hessen, 65760, Germany* *SRN_DE-AR-000005685*
Product group :	*Impression Material*
Device/Trade name :	*DENU Light Body*
Model name	*DENU Light Body Regular, DENU Light Body Fast*
GMDN Code	*35866*
Basic UDI-DI	*88000154211MP*
Classification	*Class Ⅰ by Rule 1 of Annex Ⅷ, MDR 2017/745*
Conformity assessment route	*AnnexⅠ+AnnexⅡ+AnnexⅢ, MDR 2017/745*

We hereby declare that the above-mentioned medical devices meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. This EU Declaration of Conformity is issued under sole responsibility of HDI Inc. and according to Annex IV of the referred Regulation. All supporting documentation is retained under the premises of the manufacturer.

Attachment: Intended purpose, Product code and Applied standards

CE

Taekyou Kim

CEO, HDI Inc.
Gyeonggi-do, Korea
July 24, 2023

■ Intended Purpose

Material for impression taking

■ Product Code

No.	Product Code	Description
1	HDI21001	Denu Light Body Regular 4 Cartridge
2	HDI21003	Denu Light Body Fast 4 Cartridge
3	HDI21005	Denu Light Body Regular Tube
4	HDI21006	Denu Light Body Fast Tube

■ Applied standards

No.	Standard No.	Standard Name	Ratification
1	MDR 2017/745	EU Regulation 2017/745 of the european parliament and of the council	2017
2	EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016
3	ISO 14971	Medical devices - Application of risk management to medical devices	2019
4	EN ISO 20417	Medical device-Information Supplied by the Manufacturer	2021
5	EN ISO15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements Remains Current [Superseded:CEN EN 980]	2016
6	EN ISO 4823	Dentistry – Elastomeric impression and bite registration materials	2021
7	EN 1641	Dentistry - Medical devices for dentistry – Materials	2009
8	EN ISO 7405	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry	2018
9	EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2015
10	EN ISO10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2018
11	EN ISO10993-5	Biological evaluation of medical devices - Part 5: Test for in vitro cytotoxicity	2009
12	EN ISO10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity	2013
13	EN ISO10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2018
14	MEDDEV 2.7.1 Rev.4	Guidelines on Medical Devices Clinical Evaluation	2016
15	MEDDEV 2.12.1 Rev.8	Guidelines on Medical Devices Vigilance System	2013
16	ISTA 2A	International Safe Transit Association Standards	2016

EC DECLARATION OF CONFORMITY

Manufacturer :	*HDI Inc.* *A-504, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13209 Republic of Korea* *SRN_KR-MF-000026600*
EU Representative :	*KTR Europe GmbH* *Mergenthalerallee 77, Eschborn, Hessen, 65760, Germany* *SRN_DE-AR-000005685*
Product group :	*Impression Material*
Device/Trade name :	*DENU Putty Set*
Model name	*DENU Putty Set Regular, DENU Putty Set Fast*
GMDN Code	*35866*
Basic UDI-DI	*88000154213MT*
Classification	*Class Ⅰ by Rule 1 of Annex Ⅷ, MDR 2017/745*
Conformity assessment route	*AnnexⅠ+AnnexⅡ+AnnexⅢ, MDR 2017/745*

We hereby declare that the above-mentioned medical devices meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. This EU Declaration of Conformity is issued under sole responsibility of HDI Inc. and according to Annex IV of the referred Regulation. All supporting documentation is retained under the premises of the manufacturer.

Attachment: Product code and applied standards

CE

Taekyou Kim

CEO, HDI Inc.
Gyeonggi-do, Korea
Apr 01, 2024

■ Intended Purpose

Material for impression taking

■ Product Code

No.	Product Code	Description
1	HDI21017	Denu Putty Set Regular 560ml
2	HDI21018	Denu Putty Set Fast 560ml
3	HDI21019	Denu Putty Set Regular 660ml
4	HDI21020	Denu Putty Set Fast 660ml

■ Applied standards

No.	Standard No.	Standard Name	Ratification
1	MDR 2017/745	EU Regulation 2017/745 of the european parliament and of the council	2017
2	EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016
3	ISO 14971	Medical devices - Application of risk management to medical devices	2019
4	EN ISO 20417	Medical device-Information Supplied by the Manufacturer	2021
5	EN ISO15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements Remains Current [Superseded:CEN EN 980]	2016
6	EN ISO 4823	Dentistry – Elastomeric impression and bite registration materials	2021
7	EN 1641	Dentistry - Medical devices for dentistry – Materials	2009
8	EN ISO 7405	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry	2018
9	EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2015
10	EN ISO10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2018
11	EN ISO10993-5	Biological evaluation of medical devices - Part 5: Test for in vitro cytotoxicity	2009
12	EN ISO10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity	2013
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14	MEDDEV 2.7.1 Rev.4	Guidelines on Medical Devices Clinical Evaluation	2016
15	MEDDEV 2.12.1 Rev.8	Guidelines on Medical Devices Vigilance System	2013
16	ISTA 2A	International Safe Transit Association Standards	2016

Regierungspräsidium Kassel

HESSEN

Freiverkaufszertifikat

nach Artikel 60 der Verordnung (EU) 2017/745

und § 10 des
Medizinprodukterecht-Durchführungsgesetzes

in der jeweils geltenden Fassung

zur Vorlage bei den zuständigen Behörden / Stellen

Es wird bescheinigt, dass der

Bevollmächtigter

KTR Europe GmbH
Mergenthalerallee 77
65760 Eschborn
Deutschland

seine eingetragene Niederlassung in Deutschland hat und dass die gemäß der

Verordnung (EU) 2017/745
vom 05. April 2017
über Medizinprodukte

in der jeweils geltenden Fassung mit einem CE-Kennzeichen versehenen Produkte in der Union gehandelt werden dürfen.

Produkt/e:
Produktname

- **Siehe Anlage**

Im Auftrag
Kassel, 05. August 2024

REGIERUNGSPRÄSIDIUM KASSEL 31

M. Reimers
(Reimers)
Dezernat 56 – 53 o 12 (080-00185-2)

Free Sales Certificate

according to Article 60 of Regulation (EU) 2017/745

and section 10 of the
Medical Devices Law Implementing Act

as amended

for presentation to the competent authorities / bodies

It is also certified that the

Authorised Representative

KTR Europe GmbH
Mergenthalerallee 77
65760 Eschborn
Germany

has its registered place of business in Germany and the devices bearing the CE marking in accordance with the

Regulation (EU) 2017/745
of 05 April 2017
on medical devices

as amended may be marketed in the Union.

Device/s:
Device name

- **See Annex**

Produktliste Freiverkaufszertifikat

Attachment Free Sales Certificate

Produktname *Produktbeschreibung*	Produkt-ID	Basis-UDI-DI	Nummer der Bescheinigung der Benannten Stelle	Produktionsstätte (siehe letzte Seite)
Product name *Product description*	***Product ID***	***Basic UDI-DI***	***Number of the certificate by the notified body***	***Production facility (see last page)***
Denu Light Body Regular 4 Cartridge Impression Materials	HDI21001	88000154211MP	N/A	1
Denu Light Body Fast 4 Cartridge Impression Materials	HDI21003	88000154211MP	N/A	1
Denu Light Body Regular Tube Impression Materials	HDI21005	88000154211MP	N/A	1
Denu Light Body Fast Tube Impression Materials	HDI21006	88000154211MP	N/A	1
Denu Heavy Body Regular 4 Cartridge Impression Materials	HDI21007	88000154211MP	N/A	1
Denu Heavy Body Fast 4 Cartridge Impression Materials	HDI21009	88000154211MP	N/A	1
Denu Heavy Body Regular Tube Impression Materials	HDI21011	88000154211MP	N/A	1
Denu Heavy Body Fast Tube Impression Materials	HDI21012	88000154211MP	N/A	1
Denu Medium Body Regular 4 Cartridge Impression Materials	HDI21013	88000154212MR	N/A	1
Denu Medium Body Fast 4 Cartridge Impression Materials	HDI21015	88000154212MR	N/A	1
Denu Putty Set Regular 560ml Impression Materials	HDI21017	88000154213MT	N/A	1
Denu Putty Set Fast 560ml Impression Materials	HDI21018	88000154213MT	N/A	1
Denu Putty Set Regular 660ml Impression Materials	HDI21019	88000154213MT	N/A	1
Denu Putty Set Fast 660ml Impression Materials	HDI21020	88000154213MT	N/A	1
Denu Bite Sil Impression Materials	HDI21021	88000154214MV	N/A	1
Denu Trans Sil Impression Materials	HDI21022	88000154215MX	N/A	1
Denu GingiCord #000 (black) GINGIVAL RETRACTION CORD, NON-MEDICATED	HDI22001	88000154225Z	N/A	1
Denu GingiCord #00 (brown) GINGIVAL RETRACTION CORD, NON-MEDICATED	HDI22002	88000154225Z	N/A	1
Denu GingiCord #0 (purple) GINGIVAL RETRACTION CORD, NON-MEDICATED	HDI22003	88000154225Z	N/A	1

Produktliste Freiverkaufszertifikat

Attachment Free Sales Certificate

Produktname *Produktbeschreibung* ***Product name*** *Product description*	Produkt-ID ***Product ID***	Basis-UDI-DI ***Basic UDI-DI***	Nummer der Bescheinigung der Benannten Stelle ***Number of the certificate by the notified body***	Produktionsstätte (siehe letzte Seite) ***Production facility (see last page)***
Denu GingiCord #1 (blue) GINGIVAL RETRACTION CORD, NON-MEDICATED	HDI22004	88000154225Z	N/A	1
Denu GingiCord #2 (green) GINGIVAL RETRACTION CORD, NON-MEDICATED	HDI22005	88000154225Z	N/A	1
Denu Speedy Stat GINGIVAL RETRACTION SOLUTION	HDI22013	88000154221MS	N/A	1
Denu Block-Out Resin DENTAL APPLIANCE FABRICATION MATERIAL, RESIN	HDI31001	880001543162	N/A	1
Denu Dam GINGIVA BLEACHING PROTECTOR	HDI42001	880001544267	N/A	1
Denu Vaseline DENTAL FABRICATION BARRIER DRESSING	HDI37002	88000154376E	N/A	1
Denu EDTA Cream NON-STERIL ENDODONTIC CLEANING AND IRRIGATION MATERIALS	HDI38001	88000154386G	N/A	1
Denu Fluoride Gel Peach ORAL HYGIENE AND PREVENTIVE MATERIAL	HDI44001	88000154446B	N/A	1
Denu Fluoride Gel Strawberry ORAL HYGIENE AND PREVENTIVE MATERIAL	HDI44002	88000154446B	N/A	1
Denu Fluoride Gel Orange ORAL HYGIENE AND PREVENTIVE MATERIAL	HDI44003	88000154446B	N/A	1
Denu Fluoride Gel Mint ORAL HYGIENE AND PREVENTIVE MATERIAL	HDI44004	88000154446B	N/A	1
Denu Fluoride Gel Tray Large 25pcs DISPOSABLE FLUORIDE GEL TRAY	HDI45001	88000154456D	N/A	1
Denu Fluoride Gel Tray Large 100pcs DISPOSABLE FLUORIDE GEL TRAY	HDI45002	88000154456D	N/A	1
Denu Fluoride Gel Tray Medium 25pcs DISPOSABLE FLUORIDE GEL TRAY	HDI45003	88000154456D	N/A	1
Denu Fluoride Gel Tray Medium 100pcs DISPOSABLE FLUORIDE GEL TRAY	HDI45004	88000154456D	N/A	1
Denu Fluoride Gel Tray Small 25pcs DISPOSABLE FLUORIDE GEL TRAY	HDI45005	88000154456D	N/A	1
Denu Fluoride Gel Tray Small 100pcs DISPOSABLE FLUORIDE GEL TRAY	HDI45006	88000154456D	N/A	1

Produktliste Freiverkaufszertifikat

Attachment Free Sales Certificate

Produktname *Produktbeschreibung*	**Produkt-ID**	**Basis-UDI-DI**	**Nummer der Bescheinigung der Benannten Stelle**	**Produktionsstätte** (siehe letzte Seite)
Product name *Product description*	***Product ID***	***Basic UDI-DI***	***Number of the certificate by the notified body***	***Production facility (see last page)***
Denu Pumice Paste with Fluoride DENTAL ABRASIVE AND POLISHING MATERIALS	HDI47001	88000154476H	N/A	1
Denu Pumice Paste without Fluoride DENTAL ABRASIVE AND POLISHING MATERIALS	HDI47002	88000154476H	N/A	1
Denu Jig Handy DENTAL APPLIANCE FABRICATION MATERIAL, RESIN	HDI48001	88000154486K	N/A	1
Denu Jig Paste DENTAL APPLIANCE FABRICATION MATERIAL, RESIN	HDI48002	88000154486K	N/A	1
Denu Stick Free DENTAL MATERIAL APPLICATION TOOL	HDI51001	880001545168	N/A	1
Denu Plastic Probe CP12 DENTAL INSTRUMENT	HDI52001	88000154526A	N/A	1
Denu Plastic Probe UNC DENTAL INSTRUMENT	HDI52002	88000154526A	N/A	1
Denu Shim Stock DENTAL ARTICULATION PAPER	HDI53001	88000154536C	N/A	1

Weitere Produktionsstätten
Other production facilities

No.	Organization	Address
1.	HDI Inc.	A-504, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Gyeonggi-do 13209 Seongnam-si Republic of Korea


REGIERUNGSPRÄSIDIUM KASSEL
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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Land: Country / Pays :	Bundesrepublik Deutschland
Diese öffentliche Urkunde This public document / Le présent acte public	
2. ist unterschrieben von has been signed by / a été signé par	Herr Reimers
3. in seiner/ihrer Eigenschaft als acting in the capacity of / agissant en qualité de	Technischer Angestellter
4. sie ist versehen mit dem Siegel / Stempel des (der) bears the seal / stamp of / est revêtu du sceau / timbre de	Regierungspräsidium Kassel

Bestätigt
Certified / Attesté

5. in at / à	Kassel	**6. am** the / le	08.08.2024
7. durch by / par	das Regierungspräsidium Kassel		
8. unter Nr. N° / sous n°	3389/2024		
9.Siegel/Stempel: Seal / stamp: / Sceau / timbre :	REGIERUNGSPRÄSIDIUM KASSEL 81	**10.Unterschrift:** Signature: / Signature :	Peter


REGIERUNGSPRÄSIDIUM KASSEL