

ITENA CLINICAL
Central Parc, Batiment B 97 Allée De La Louve
93420 Villepinte Fr - France
09/07/2024

Notified Body Confirmation Letter
Reference: 145501

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, ICIM SPA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0425 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

ITENA CLINICAL
Central Parc, Batiment B 97 Allée De La Louve
93420 Villepinte Fr - France

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,
ICIM SPA
Piazza Don Enrico Mapelli, 75
2099 Sesto San Giovanni MI

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

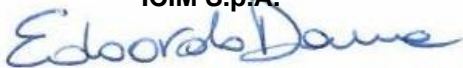
Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Dental glass fiber post for endodontic restoration - DENTOCLIC - Glass fiber posts	Class IIa	N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
Dental titanium posts for endodontic restoration - DENTOCLIC - Titanium and stainless steel posts	Class IIa	N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
Dental drills for endodontic restoration - DENTOCLIC - Drills and Reamers	Class IIa	N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
Polymer-based filling restorative materials - REFLECTYS and REFLECTYS FLOW	Class IIa	N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
Glass fiber ceramic disk and blocs - NUMERYS GF	Class IIa	N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
Hybrid ceramic disk and blocs - NUMERYS HC	Class IIa	N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
Bioceramic reparative cement - MTA BIOREP	Class IIb excluding Class IIb implantable	N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
Bioceramic root canal filler - MTA BIOSEAL	Class IIb excluding Class IIb implantable	N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
Temporary crowns and bridges - DENTOCROWN HD	Class IIa	N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
Temporary cement - PROVITEMP and DENTOTEMP	Class IIa	N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
Dentocore - Restorative Cement	Class IIa	N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425

Device name or Basic UDI-DI (under MDR application)	MDR classification proposed by the manufacturer and verified at the pre-application stage)	Device (as proposed by the manufacturer and verified at the pre-application stage)	If the device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Dentocore Body - Restorative Cement	Class IIa		N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
PREVENT SEAL Self-etching light cured pit & fissure sealant	Class IIa		N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
DENTAL COMPOSITE RESIN	Class IIa		N/A	Certificate N. MED-004026-00; Letter N. BO/2022/003657/LG-md NB ICIM SPA CE 0425
TOTAL CEM TOTAL CRAM				

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
08/05/2023	REV.00	Initial issue
19/03/2024	REV.01	Addition of device: PREVENT SEAL Self-etching light cured pit & fissure sealant
04/06/2024	REV.02	Addition of device: DENTAL COMPOSITE RESIN
09/07/2024	REV.03	Added Clearer specification for the device DENTAL COMPOSITE RESIN

Mr. Edoardo Dossena
Sales Manager Straytegic Industry
ICIM S.p.A.



Miss. Flavia Lepore
Sales Director
ICIM S.p.A.





Manufacturer's Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	ITENA CLINICAL
Manufacturer address and contact details	Central Parc, 97 Allée de la Louve 93420 Villepinte FRANCE
Single Registration Number (SRN) (if available)	FR-MF-000011957

Notified body name	ICIM
Notified body number	0425
Directive Certificate number(s) to which this confirmation is made	MED-004026-00
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26/05/2024
End date of extended validity/transition period	31/12/2028

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.



We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*
 - Expired *before* 20 March 2023:
 - Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device
 - A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)
 - A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)
 - Expired/expires *after* 20 March 2023:
 - A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
 - We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body



➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

• *Choose one applicable statement:*

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

ITENA CLINICAL

Villepinte, 27 septembre 2024

Olivier Lafarge, CEO

Sign:

ITENA CLINICAL
Central Parc - Bât. B
97 Allée de la Louve
93420 VILLEPINTE - FRANCE
Siret 522 824 689 000 64



Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Notified Body name and number	End date of extended validity/transition period	Substitute Device (if applicable)
DENTOCLIC Glass fiber post	MED-004026-00	26/05/2024	<u>ICIM 0425</u>	<u>31/12/2028</u>	<u>NA</u>
DENTOCLIC Titanium post	MED-004026-00	26/05/2024	<u>ICIM 0425</u>	<u>31/12/2028</u>	<u>NA</u>
DENTOCLIC Stainless steel post	MED-004026-00	26/05/2024	<u>ICIM 0425</u>	<u>31/12/2028</u>	<u>NA</u>
DENTOCLIC Drills	MED-004026-00	26/05/2024	<u>ICIM 0425</u>	<u>31/12/2028</u>	<u>NA</u>
DENTOCLIC Gates reamers	MED-004026-00	26/05/2024	<u>ICIM 0425</u>	<u>31/12/2028</u>	<u>NA</u>
DENTOCLIC Largo reamers	MED-004026-00	26/05/2024	<u>ICIM 0425</u>	<u>31/12/2028</u>	<u>NA</u>
REFLECTYS	MED-004026-00	26/05/2024	<u>ICIM 0425</u>	<u>31/12/2028</u>	<u>NA</u>
REFLECTYS FLOW	MED-004026-00	26/05/2024	<u>ICIM 0425</u>	<u>31/12/2028</u>	<u>NA</u>
MTA BIOREP	MED-004026-00	26/05/2024	<u>ICIM 0425</u>	<u>31/12/2028</u>	<u>NA</u>



MTA BIOSEAL	MED-004026-00	26/05/2024	<u>ICIM</u> <u>0425</u>	<u>31/12/2028</u>	<u>NA</u>
TOTAL CEM	MED-004026-00	26/05/2024	<u>ICIM</u> <u>0425</u>	<u>31/12/2028</u>	<u>NA</u>
TOTAL CRAM	MED-004026-00	26/05/2024	<u>ICIM</u> <u>0425</u>	<u>31/12/2028</u>	<u>NA</u>
PROVITEMP	MED-004026-00	26/05/2024	<u>ICIM</u> <u>0425</u>	<u>31/12/2028</u>	<u>NA</u>
DENTOTEMP	MED-004026-00	26/05/2024	<u>ICIM</u> <u>0425</u>	<u>31/12/2028</u>	<u>NA</u>
NUMERYYS HC	MED-004026-00	26/05/2024	<u>ICIM</u> <u>0425</u>	<u>31/12/2028</u>	<u>NA</u>
NUMERYYS GF	MED-004026-00	26/05/2024	<u>ICIM</u> <u>0425</u>	<u>31/12/2028</u>	<u>NA</u>
DENTOCROWN HD	MED-004026-00	26/05/2024	<u>ICIM</u> <u>0425</u>	<u>31/12/2028</u>	<u>NA</u>
DENTOCORE	MED-004026-00	26/05/2024	<u>ICIM</u> <u>0425</u>	<u>31/12/2028</u>	<u>NA</u>
DENTOCORE BODY	MED-004026-00	26/05/2024	<u>ICIM</u> <u>0425</u>	<u>31/12/2028</u>	<u>NA</u>
PREVENT SEAL	MED-004026-00	26/05/2024	<u>ICIM</u> <u>0425</u>	<u>31/12/2028</u>	<u>NA</u>



0425



Approvazione del Sistema Completo di Garanzia di Qualità

Full quality assurance system approval

Certificato N. **0425-MED-004026-00**
Certificate No.

Secondo l'allegato II, escluso (4) della Direttiva Europea 93/42/CEE (recepita con il Dlg n. 46 del 24.02.97)
According to Annex II, excluding (4) of EC Directive 93/42/CEE (as transposed into Dlg n. 46 issued on 24.02.97)

ORGANISMO NOTIFICATO / NOTIFIED BODY

ICIM S.p.A. - Identification number: 0425
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY

VISTO L'ESITO DELLE VERIFICHE CONDOTTE IN CONFORMITÀ ALL'ALLEGATO II ESCLUSO (4) DELLA DIRETTIVA EUROPEA 93/42/CEE DICHIARA CHE IL SISTEMA COMPLETO DI GARANZIA DELLA QUALITÀ ATTUATO DA:
ON THE BASIS OF THE ASSESSMENT PERFORMED ACCORDING TO ANNEX II EXCLUDING (4) OF EC DIRECTIVE 93/42/CEE DECLARES THAT THE FULL QUALITY ASSURANCE SYSTEM ENFORCED BY:

ITENA CLINICAL

Sede Legale

188 Avenue Victor Hugo -75016 Paris - France

Sede Operativa

31 Avenue Georges Clémenceau - 93420 Villepinte - France

PER I SEGUENTI TIPI DI PRODOTTI, PROCESSI, SERVIZI
FOR THE FOLLOWING KINDS OF PRODUCTS, PROCESSES, SERVICES

Materiali dentali e dispositivi medici per scopi odontoiatrici
Dental materials and medical devices for dentistry purpose

È CONFORME AI REQUISITI / IS IN COMPLIANCE WITH REQUIREMENTS

Allegato II ESCLUSO (4) della Direttiva Europea 93/42/CEE
Annex II EXCLUDING (4) of EC Directive 93/42/EEC

Per l'identificazione dei modelli di prodotto vedere l'Allegato / For identification of the model type see Annex

Il presente Certificato è da ritenersi valido solo se accompagnato dal relativo Allegato / This Certificate is valid only with the relative Annex

Gaetano Trizio
Rappresentante Direzione / Management Representative

ICIM S.p.A.

PRIMA EMISSIONE
FIRST ISSUE

15/07/2020

EMISSIONE CORRENTE
CURRENT ISSUE

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IDENTIFICAZIONE TIPOLOGIE E MODELLI IDENTIFICATION OF THE MODEL/TYPE

Care & Prevention / Prevenzione e Profilassi

Prevention / Prevenzione		
Prevent Seal – Class IIa	PVSEAL-1.2 PVSEAL ECHPVSEAL	Fissure sealent / Sigillante per piccole cavità e per solchi
Klirich – Class IIa	KKLIRC2S KLIR-T3M KLIR-T3XP	Periodontal gel / Gel Parodontale

Restorative dentistry / Odontoiatria Restaurativa

Resin for temporary reconstruction / Resina per restauri provvisori		
Dentocrown HD – Class IIa	DWNHD50-A1 DWNHD50-A2 DWNHD50-A3	Self-curing resin for temporary crown and bridges / Resina Composita autopolimerizzante per protesi fisse provvisorie

Restorative cement / Cemento per Odontoiatria Conservativa		
Dentocore Body– Class IIa	DCBODY-50 DABODY1-10 DABODY3-VP ECHDCBODY	Core build-up cementation composite / Composito resinoso dual core per il build-up
Dentocore – Class IIa	DCSAK1 DCB-50 DCA3-50	Core build-up cementation composite / Composito resinoso dual core per il build-up

Gaetano Trizio
Rappresentante Direzione / Management Representative

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Cement / Cemento		
Provitemp – Class IIa	PTEMP1-10 ECHPVTEMP PTEMP2-VP	Short term temporary cement / Cemento provvisorio per la cementazione provvisoria
Dentotemp – Class IIa	DT-2.10 DTCA2-20 DTCA1-5 DTCA4-VP ECHDTP	Long term temporary cement / Cemento provvisorio per la cementazione provvisoria-prolungata
Dentocem – Class IIa	DCA-2.5	Permanent resin cement / Cemento resinoso per la cementazione definitiva
Totalcem – Class IIa	TTLCEM-A2 TTLCEM-TR TCEM3-VPA2 TCEM3-VPTR ECHTLCEM	Self-etching permanent resin cement / Cemento-resina automordenzante permanente
Total C-RAM – Class IIa	TTCRAM-TR TTCRAM-OD TTCRAM-BLC ECHTCRAM ECHTCR-BLC	Self-etching permanent resin cement / Cemento-resina automordenzante permanente
MTA BIOREP – Class IIb	MTA-BRP2.2 MTA-BRP5.5	Bioceramic reparative cement / Cemento bioceramico riparativo
Tooth Filling / Otturazione dentale (materiali per)		
Reflectys – Class IIa	SRTYS-XXX/CPTYS-XXX with XXX the different shades ECHSRTYSA2	Universal composite / compositi dentali universali

Gaetano Trizio
Rappresentante Direzione / Management Representative

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	ECHRFLTYS ECHCPTYS	
Reflectys Flow – Class IIa	FWTYS-XXX with XXX the different shades	Universal fluid composite / compositi dentali fluidi universali

Root Canal sealer / Cemento canalare (Sigillante)		
MTA Bioseal – Class IIb	MTA-BSEAL ECHBSEAL	Bioceramic root canal sealer / Cemento bioceramico riparativo per canali radicolari
Obturyrs – Class IIa	OBHM1-5 OBAX1-5 ECHOBY5	Permanent root canal sealer / Cemento per trattamenti Endodontici con sigillo permanente dei canali radicolari

Posts / Perni		
Dentoclic Titanium Posts (IIa)	Tlyx20-z With x= L is the post a long model, y= the color of the post according to it's diameter, z= number ranging from 0 to 5	Sanded titanium Posts / Perni endodontici in Titanio
Dentoclic Stainless Steel Posts (IIa)	Dlx20y-z Clx20y-z DCLAIy-z CCLAI10 With x= L if the post is a long model, y= the color of the post according to its diameter, z= length of the post in mm	Stainless Steel post (cilindro-conical / conical / Lock) / Perni endodontici in Acciaio(cilindro-conici/conici/Lock)
X-CELLIUM Stainless Steel Posts – Class IIa	KCELLIUM	Stainless Steel posts / Perni in acciaio inossidabile



Gaetano Trizio
Rappresentante Direzione / Management Representative

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According to Annex II, excluding (4) of EC Directive 93/42/CEE (as transposed into Dlg n. 46 issued on 24.02.97)

	<p><u>Modules:</u></p> <p>XCEL-4yz With y= the color of the post according to its diameter, z=S/M/L/XL if the post is a small/medium/long/ extra-long model</p> <p><u>Refills:</u></p> <p>XCIyz-x With y= the color of the post according to its diameter, z=M or L if the post is a medium/long model, x=length of the post</p>	
Dentoclic Glass Fiber Post (IIa)	<p>FVOx5-y FVTx5-y With x= the color of the post according to its diameter, y= the length of the post in mm</p>	Glass Fiber Posts / Perni endodontici in fibra di vetro

Drills / Frese		
	<p>FP-x with x= diameter of the drill</p> <p>FP-ASSORT</p> <p>DFx4-y with x=color of the drill corresponding to the post, y= diameter of the drill</p> <p>CF4-01 / CF4-02 CF4-MIX</p>	<p>Drills for post insertion (Dentoclic) / Frese endodontiche Dentoclic (per sagomare il canale radicolare per l'accesso degli strumenti canalari)</p>
Dentoclic Drills (Cylindro-Conical Reamers / Performance Reamers / Conical Reamers / Driver Drills) (IIa)		

Gaetano Trizio
Rappresentante Direzione / Management Representative

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	FPFx-y with x= color of the drill corresponding to the post, y= diameter of the drill	
X-CELLIUM Drills – Class IIa	XCFPy-z With y=The color of the drill according to its associated post, z= the diameter of the drill	Graduated Drills for posts insertion (X-Cellium) / Frese graduate per inserimento perni (X-Cellium)
Gates Drills – Class IIa	FGx-y with x= number of the drill, y = length of the drill (28 or 32 mm) Kit: FGASSORT-28 FGASSORT-32	Drills for root canal opening / Frese endodontiche per sagomare il terzo coronale del canale radicolare
Largo Drills – Class IIa	FLx-y with x= number of the drill, y= length of the drill (28 or 32 mm) Kit: FLASSORT-28 FLASSORT-32	Drills for root canal opening / Frese endodontiche per sagomare il terzo coronale del canale radicolare

Tooth surface treatment / Trattamento delle superfici dentali

Dentoetch – Class IIa	DE-4.12 DETCHE-VP	Tooth Etching gel / Gel mordenzante di smalto e dentina
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Ceramic surface treatment / Trattamento delle superfici ceramiche

Ceram-Etch – Class IIa	CRAM-ETCH	Buffered hydrofluoric acid gel for ceramics / Gel tamponato all'acido fluoidrico per ceramiche
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Gaetano Trizio
Rappresentante Direzione / Management Representative

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Approvazione del Sistema Completo di Garanzia di Qualità *Full quality assurance system approval*

ALLEGATO AL / ANNEX TO

Certificato N.
Certificate No.

0425-MED-004026-00

Secondo l'allegato II, escluso (4) della Direttiva Europea 93/42/CEE (recepita con il Dlg n. 46 del 24.02.97)
According to Annex II, excluding (4) of EC Directive 93/42/CEE (as transposed into Dlg n. 46 issued on 24.02.97)

Bonding agent		
Silan-It – Class IIa	SILAN-IT	Silane coupling agent / Primer adesivo monocomponente
Iperbond Max – Class IIa	IBONDMAX5	Universal adhesive for dental restoration / Primer Adesivo per adesione smalto-dentinale nell'Odontoiatria Restaurativa
Quick Bond – Class IIa	DBQAB-10 DBQAK DBQAP-10	Dentine bonding agent/set - Primer Adesivo automordenzante per dentina/set
Bond Activator – Class IIa	DBAC-7	Dentine bonding agent/set - Primer Adesivo automordenzante per dentina (tecnica adesiva)/set
C-RAM Booster – Class IIa	CRAMBST5	Dentin Adhesive / Adesivo Dentinale

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Prosthetic dentistry / Odontotria Protesica

CAD/CAM Prosthetic / Protesi con metodologia CAD/CAM		
Numerys HC – Class IIa	NYS-12A1 / NYS-12A2 NYS-12A3 / NYS-12A3.5 NYS-12B3 / NYS-12E NYS-14A1 / NYS-14A2 NYS-14A3 / NYS-14A3.5 NYS-14B3 / NYS-14E NYS-D16A2 / NYS-D16A3 NYS-D16A35/ NYS-D16B3 NYS-D16E	Hybrid ceramic for CAD/CAM - Ceramica ibrida per CAD-CAM
Numerys GF – Class IIa	NYSGF-BCS NYSGF-DSK NYSGF-LAB10	Glass fiber CAD/CAM composite - Fibra di vetro per CAD-CAM

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