EC Certificate Full Quality Assurance System: Certificate CH19/0994

The management system of

Produits Dentaires SA

18 rue des Bosquets
CH-1800 Vevey

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

MAP System Non sterile endodontic material placement instrument
Non sterile Mineral based filling dental material
Non sterile calcium hydroxide based dental filling material
Non-sterile zinc oxide based dental cements for endodontic and restorative applications
Non sterile dental fiber post
Non sterile Dental desobturating material
Non sterile endodontic cleaning and irrigation materials
Non sterile dental Drills and reamers
Non-sterile root canal irrigation cannulae.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 25 May 2021 until 8 June 2023
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 10 June 2012.

Certification is based on reports numbered CH/GE 3205871

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com

Notified Body Confirmation Letter
Reference: contract n. 150931-155597/25

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, 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:

Produits Dentaires SA
Rue des Bosquets 18,
1800, Vevey, Switzerland

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 ICIM 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 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 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

ICIM SpA Società soggetta all'attività di direzione e coordinamento di ICIM GROUP Srl
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Capitale sociale € 260.000,00 int. versato ed esistente - C.F./P.IVA e Iscriz. Reg. Imprese di Milano n. 12908230159 – R.E.A. n. 1596292

- 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
20099 Sesto San Giovanni MI
Identification on NANDO CE0425

Table 1: Devices covered by this letter and for which ICIM SPA 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
EDTA - Non sterile endodontic cleaning and irrigation material	Class IIa	N/A	Certificate CH19/0994 Notified Body CE 1639
MTA- Non sterile mineral based filling dental material	Class IIa	N/A	Certificate CH19/0994 Notified Body CE 1639
Fibrapost - Non sterile dental fiber post	Class IIa	N/A	Certificate CH19/0994 Notified Body CE 1639
Eugenate Desobturator - Non sterile dental desobturating material	Class IIa	N/A	Certificate CH19/0994 Notified Body CE 1639
OPACAL-Non sterile calcium hydroxide based dental filling material	Class IIa	N/A	Certificate CH19/0994 Notified Body CE 1639

Table 2: Devices covered by this letter and for which ICIM SPA is NOT 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

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
10/02/2024	01	Update Agreement with SGS and Manufacturer
2024/09/24	00	Initial issue

Remaining at your disposal for any clarification on the content of this letter, we take this opportunity to extend our best regards.

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

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

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Manufacturer's Declaration

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

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- 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	Produits Dentaires SA
Manufacturer address and contact details	Rue de Bosquets 18, 1800 Vevey, Switzerland
Single Registration Number (SRN)	CH-MF-000023147

Authorised Representative name	PD Dental EU
Authorised Representative address and contact details	Rue des Arcouasses 4, 74200 Thonon-les-Bains, France
Single Registration Number (SRN)	FR-AR-000017144

Notified body name (if applicable)	SGS Belgium NV
Notified body number (if applicable)	CE 1639
Directive Certificate number(s) to which this confirmation is made (if applicable)	CH19/0994
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	08.06.2023
End date of extended validity/transition period	31.12.2027 or 31.12.2028 (See attached schedule of devices for more details)

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- 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 covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.
  - Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made by us to a notified body for the devices listed in the attached schedule and signed written agreement(s) is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR
- **Quality Management System (QMS)**
  - A QMS in accordance with Article 10(9) MDR is in place.
- **Device(s) as listed in the attached schedule**
  - The devices continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices 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:

Produits Dentaires SA

Vevey, 14.02.2025

Silvia Contini, Quality & Compliance Manager

regulatory@pd-dental.com

PRODUITS DENTAIRES S.A.
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Schedule of Devices

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

Identification of the device(s)[1] (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 (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**
EDTA - Non sterile endodontic cleaning and irrigation material	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	ICIM Spa / CE 0425	31.12.2028
MTA- Non sterile mineral based filling dental material	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	ICIM Spa / CE 0425	31.12.2028
Fibrapost - Non sterile dental fiber post	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	ICIM Spa / CE 0425	31.12.2028
Eugenate Desobturator - Non sterile dental desobturating material	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	ICIM Spa / CE 0425	31.12.2028
OPACAL – Non sterile calcium hydroxide based dental filling material	CH19/0994	08.06.2023	SGS Belgium NV / CE 1639	ICIM Spa / CE 0425	31.12.2028

[1] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)