

## ATTESTATION CE / EC CERTIFICATE

Approbation du Système d'assurance Qualité de la Production / Approval of Production Quality Assurance System

ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

Pour les dispositifs de classe IIb ou III, un certificat CE de type est requis

For class IIb or III devices, a EC type certificate is required

Fabricant / Manufacturer

**SEPTODONT**

**58 rue du Pont de Créteil**

**94107 SAINT MAUR DES FOSSES CEDEX FRANCE**

Catégorie du(des) dispositif(s) / Device(s) category

**Dispositifs non injectables à usage professionnel dentaire, stériles et non stériles.**

*Non injectable medical devices for professional dental use, sterile and non sterile.*

Voir document complémentaire GMED / See GMED additional document

**n° 36996**

**GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600936 - P600252, le système d'assurance qualité - pour la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.**

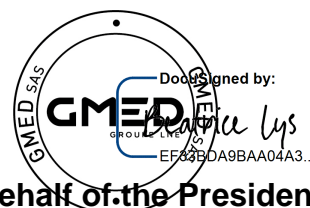
*GMED certifies that, on the basis of the results contained in the file referenced P600936 - P600252, the quality system - for manufacturing and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex V section 3.*

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

**Début de validité / Effective date : May 21st, 2021 (included)**

**Valable jusqu'au / Expiry date : May 26th, 2024 (included)**



**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

Ce document complémentaire GMED n° 36996 rev. 7 atteste de la validité du certificat CE n° 9054 rev. 33 au regard des informations listées ci-dessous.

*This GMED additional document N° 36996 rev. 7 attests to the validity of CE certificate n° 9054 rev. 33 with regard to the information listed below.*

Fabricant / Manufacturer:

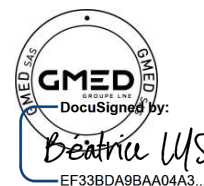
**SEPTODONT**  
58 rue du Pont de Créteil  
94107 SAINT MAUR DES FOSSES CEDEX  
FRANCE

**Identification des dispositifs / Identification of devices**

NOM COMMERCIAL BRAND NAME	DESCRIPTION	CLASSE DU DM MD CLASS
ENDOMETHASONE Liquide / <i>Liquid</i>	Ciment dentaire de type oxyde de zinc-eugénol <i>Zinc oxide eugenol dental cement</i>	Ila
GUTTASOLV	Solution d'élimination des matériaux d'obturation dans les canaux radiculaires <i>Root canal filling-removal solution</i>	Ila
HYDROL	Solution de nettoyage dentaire <i>Dental tooth-cleaning solution</i>	Ila
SEPTOJECT SEPTOJECT XL SEPTOJECT Evolution BADIJECT XL	Aiguille pour seringue dentaire, à usage unique <i>Dental syringe needle, single-use</i>	Ila
ALVEOGL	Pansement parodontal <i>Periodontal dressing</i>	Ila

**GMED 0459**

GMED - 36996 rev. 7  
Modifie le document n° 36996 rev. 6



On behalf of the President  
**Béatrice LYS**  
Technical Director

NOM COMMERCIAL BRAND NAME	DESCRIPTION	CLASSE DU DM MD CLASS
ENDOSOLV	Solution d'élimination des matériaux d'obturation dans les canaux radiculaires <i>Root canal filling-removal solution</i>	Ila
ENDOMETHASONE N	Ciment dentaire à l'oxyde de zinc eugénol <i>Zinc oxide eugenol dental cement</i>	III

### Sites couverts et Activités / Locations and Activities

✚ 58, Rue du Pont de Créteil - 94107 SAINT MAUR DES FOSSES CEDEX – France :  
Headquarters, manufacturing

✚ 58, Rue du Pont de Créteil - 94100 SAINT MAUR DES FOSSES – France :  
Manufacturing

✚ 103-105 avenue Beurepaire - 94100 SAINT MAUR DES FOSSES – France :  
Design

✚ 127 boulevard Diderot 75012 PARIS – France :  
Management, IT corporate, Marketing Corporate, European sales, communication, Regulatory affairs, vigilances, medical affairs

✚ 4 rue Ambroise Croizat – 77183 CROISSY BEAUBOURG – France :  
Warehouse, distribution, France and export customer services France, customer complaints, communication

### Modifications / Modifications

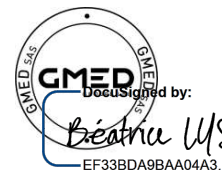
Identification des modifications apportées au certificat CE n° 9054 rev. 33:

*Identification of the modifications made to the CE certificate n° 9054 rev. 33:*

Modifications / Modifications	Dossier(s) / File(s) N°	Date / Date
Nouvelle référence de rapport dans le cadre du maintien de la certification <i>New file reference in the framework of the maintenance of the certification</i>	P603711	27/01/2022 01/27/2022
Mise à jour de la liste des références <i>Update of list of references</i>	P603711	27/01/2022 01/27/2022
Mise à jour de la liste des références <i>Update of list of references</i>	NA	19/01/2023 01/19/2023
Mise à jour de la liste des références <i>Update of list of references</i>	P604254	03/04/2024 04/03/2024

**GMED 0459**

GMED - 36996 rev. 7  
Modifie le document n° 36996 rev. 6



DocuSigned by:  
Béatrice LYS  
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On behalf of the President  
**Béatrice LYS**  
Technical Director



septodont

Septodont  
58 rue du Pont de Créteil  
94107 Saint-Maur-des-Fossés Cedex  
Tél. +33 (0) 1 49 76 70 00  
Fax : +33 (0) 1 48 85 54 01

## Manufacturer's Declaration

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

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and / or*
- the compliance of the devices with the conditions for the continued placing on the market and putting into service

Manufacturer name	SEPTODONT
Manufacturer address and contact details	58 rue du Pont de Créteil 94107 Saint-Maur-des-Fossés Cedex FRANCE

We, as the manufacturer declare under our sole responsibility that:

- the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met for the listed **Directive Certificate(s)** in attached schedule and / or
- being in compliance with the conditions listed in Article 120.3c of the MDR to continue placing on the market and putting into service the listed **device(s)** in the attached schedule

namely by fulfilling the following conditions:

- **Directive Certificate(s)** in the attached schedule
  - Directive Certificate(s) covering the listed device(s) were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.
  - Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made for the device(s) listed in the attached schedule and signed written agreement 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.



**septodont**

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

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- 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.

Saint-Maur-des-Fossés, 07<sup>th</sup> May 2024

Kinty BUI VAN

Person Responsible for Regulatory Compliance

### Schedule of Devices

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

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number for MDR Certification	End of the transition period
<b>BIODENTINE™ *</b>	18940 rev. 13 (Approval of full Quality Assurance System- Annex II excluding section 4)	26 May 2024	GMED : 0459	GMED : 0459	31 December 2027
	17618 rev. 11 (EC Design Examination of the product- Annex II section 4)	26 May 2024	GMED : 0459	GMED : 0459	31 December 2027
<b>BioRoot™ RCS</b>	18940 rev. 13 (Approval of full Quality Assurance System- Annex II excluding section 4)	26 May 2024	GMED : 0459	BSI : 2797	31 December 2027
	36633 rev. 2 (EC Design Examination of the product - Annex II section 4)	26 May 2024	GMED : 0459	BSI : 2797	31 December 2027
<b>ENDOMETHASONE N</b>	9054 rev. 33 (Approval of Production Quality Assurance System- Annex V section 3)	26 May 2024	GMED : 0459	GMED : 0459	31 December 2027
	37495 rev. 1 (Examination Type - Annex III)	26 May 2024	GMED : 0459	GMED : 0459	31 December 2027
<b>ENDOMETHASONE Liquid</b>	9054 rev. 33 (Approval of Production Quality Assurance System- Annex V section 3)	26 May 2024	GMED : 0459	GMED : 0459	31 December 2028

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number for MDR Certification	End of the transition period
<b>HEMOCOLLAGENE</b>	18939 rev. 9 (Approval of Production Quality Assurance System- Annex V section 3)	26 May 2024	GMED : 0459	GMED : 0459	31 December 2027
	8853 rev. 8 (Examination Type - Annex III)	21 August 2023	GMED : 0459	GMED : 0459	31 December 2027
<b>GUTTASOLV</b>	9054 rev. 33 (Approval of Production Quality Assurance System- Annex V section 3)	26 May 2024	GMED : 0459	GMED : 0459	31 December 2028
<b>ENDOSOLV</b>	9054 rev. 33 (Approval of Production Quality Assurance System- Annex V section 3)	26 May 2024	GMED : 0459	GMED : 0459	31 December 2028
<b>HYDROL</b>	9054 rev. 33 (Approval of Production Quality Assurance System- Annex V section 3)	26 May 2024	GMED : 0459	GMED : 0459	31 December 2028
<b>ALVEOGL</b>	9054 rev. 33 (Approval of Production Quality Assurance System- Annex V section 3)	26 May 2024	GMED : 0459	GMED : 0459	31 December 2027
<b>SEPTOJECT SEPTOJECT XL SEPTOJECT Evolution BADIJECT XL</b>	9054 rev. 33 (Approval of Production Quality Assurance System- Annex V section 3)	26 May 2024	GMED : 0459	BSI : 2797	31 December 2028

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number for MDR Certification	End of the transition period
<b>ULTRA SAFETY PLUS TWIST PART A / ULTRA SAFETY PLUS TWIST XL PART A</b>	36719 rev. 5 (Approval of Production Quality Assurance System- Annex V section 3)	26 May 2024	GMED : 0459	BSI : 2797	31 December 2028
<b>ULTRA SAFETY PLUS Twist Part B</b>	36785 rev. 2 (Approval of Production Quality Assurance System (related to securing and maintaining sterile conditions) -Annex V Section 3	26 May 2024	GMED : 0459	BSI : 2797	31 December 2028
<b>Racestyptine Solution</b>	N/A - Class I under MDD	/	/	BSI : 2797	31 December 2028
<b>Racegel</b>	N/A - Class I under MDD	/	/	BSI : 2797	31 December 2028
<b>Plastalgin</b>	N/A - Class I under MDD	/	/	BSI : 2797	31 December 2028
<b>Plastalgin Fast</b>	N/A - Class I under MDD	/	/	BSI : 2797	31 December 2028

\* BIODENTINE™ obtained MDR CE Certification in March 2023

Paris, le 28 février 2024  
Paris, February 28, 2024

**Lettre de confirmation émise par l'Organisme Notifié**  
**Notified Body Confirmation Letter**  
**Référence/Reference: 39453 rev. 1**

*[ENGLISH BELOW]*

A qui de droit,

**Confirmation du statut d'une demande formelle, d'un accord écrit et de la surveillance appropriée dans le cadre du règlement UE 2023/607 modifiant les règlements (UE) 2017/745 et (UE) 2017/746 en ce qui concerne les dispositions transitoires relatives à certains dispositifs médicaux et dispositifs médicaux de diagnostic in vitro.**

Cette lettre confirme que, **GMED SAS**, Organisme Notifié désigné au titre du règlement (UE) 2017/745 (ci-après : MDR) et identifié par le numéro **0459** sur NANDO, a reçu une demande formelle de certification conformément à l'annexe VII, section 4.3, premier alinéa, et a signé un accord écrit (contrat) conformément à l'annexe VII, section 4.3, deuxième alinéa dudit Règlement avec le fabricant nommé ci-dessous :

**SEPTODONT**  
**58, Rue du Pont de Créteil**  
**94100 SAINT-MAUR-DES-FOSSES**  
**France**  
**SRN : FR-MF-000016992**

Les dispositifs couverts par la demande formelle et l'accord écrit mentionnés ci-dessus sont identifiés dans les tableaux suivants. Le tableau 1 identifie les dispositifs pour lesquels une demande formelle a été reçue, un accord écrit conclu et pour lesquels GMED SAS est également responsable de la surveillance appropriée des dispositifs correspondants au titre de la directive applicable. Le tableau 2 identifie les dispositifs pour lesquels une demande de RIM a été reçue et un accord écrit conclu, mais pour lesquels GMED SAS n'est pas encore responsable de la surveillance appropriée des dispositifs correspondants au titre de la directive applicable.

Dans le cas de dispositifs couverts par des certificats délivrés au titre de la directive 90/385/CEE (AIMDD) ou de la directive 93/42/CEE (MDD) qui ont expiré après le 26 mai 2021 et avant le 20 mars 2023, sans avoir été retirés, cette lettre confirme également que le fabricant a signé l'accord écrit avant la date d'expiration desdits certificats ou a fourni la preuve qu'une Autorité Compétente d'un État Membre a accordé une dérogation conformément à l'article 59(1) du règlement (UE) 2017/745 ou a demandé conformément à l'article 97(1) du règlement (UE) 2017/745, de mettre en œuvre la procédure d'évaluation de la conformité applicable, avant le 20 mars 2023 pour les dispositifs concernés.

Les délais de transition qui s'appliquent aux dispositifs couverts par la présente lettre, sous réserve que le fabricant continue de respecter les autres conditions spécifiées à l'article 120.3 du Règlement (UE) 2017/745 (amendé par le Règlement (UE) 2023/607), sont indiqués ci-dessous :

- 26 mai 2026 pour les dispositifs implantables sur mesure de classe III
- 31 décembre 2027 pour les dispositifs de classe III et les dispositifs implantables de classe IIb à l'exclusion des technologies bien établies (WET - sutures, agrafes, obturations dentaires, appareils dentaires, couronnes dentaires, vis, coins, plaques, fils, broches, clips et connecteurs)
- 31 décembre 2028 pour les autres dispositifs de classe IIb, de classe IIa, de classe I mis sur le marché à l'état stérile, ayant une fonction de mesurage
- 31 décembre 2028 pour les dispositifs dont l'évaluation de la conformité au titre de la Directive 93/42/CEE ne nécessitait pas l'intervention d'un organisme notifié (par exemple instruments chirurgicaux réutilisables de classe I).

*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, **GMED SAS**, a Notified Body designated against Regulation (EU) 2017/745 (hereafter: MDR) and identified by the number **0459** on NANDO, has received a formal application for certification in accordance with Annex VII, section 4.3, first subparagraph, and has signed a written agreement (contract) in accordance with Annex VII, section 4.3, second paragraph of the said regulation with the manufacturer named below:*

**SEPTODONT**  
**58, Rue du Pont de Créteil**  
**94100 SAINT-MAUR-DES-FOSSES**  
**France**  
**SRN : FR-MF-000016992**

*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 written agreement was concluded by the date of 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 120.3 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 whose conformity assessment under Directive 93/42/EEC did not require the intervention of a notified body (e.g. class I reusable surgical instruments).

Pour le compte de GMED SAS,  
On behalf of GMED SAS,

DocuSigned by:  
*Laure Lefebvre*  
90722252442047A...

Laure LEFEBVRE  
Responsable de Département DMI CODIA  
ODSAI IMD Department Manager

**Tableau 1 : Dispositifs couverts par la présente lettre et pour lesquels GMED SAS est également responsable de la surveillance appropriée des dispositifs correspondants dans le cadre de la Directive applicable**

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

Device name and/or Basic UDI-DI (under MDR application)	Risk class of the device according to Annex VIII of Regulation (EU) 2017/745	Identification of the device certified under Directive 90/385/EEC or 93/42/EEC and intended to be substituted, if applicable	Reference(s) of the certificate(s) under Directive 90/385/EEC or 93/42/EEC
Biodentine™ 37601407000004G9	III	N/A	18940 rév 13 17618 rév 11
Hemocollagene 37601407000006GD	III	N/A	18939 rév 9 8853 rév 8
Endomethasone N 37601407000010G4	III	N/A	37495 rév 1 9054 rév 33
Endomethasone Liquid 37601407000011G6	IIa	N/A	9054 rév 33
Endosolv 37601407000023GD	IIa	N/A	9054 rév 33
Guttasolv 37601407000024GF	IIa	N/A	9054 rév 33
Hydrol 37601407000025GH	IIa	N/A	9054 rév 33
Alveogyl 37601407000018GL	III	N/A	9054 rév 33

**Tableau 2 : Dispositifs couverts par la présente lettre et pour lesquels GMED SAS n'est pas encore responsable de la surveillance appropriée des dispositifs correspondants dans le cadre de la Directive applicable**

**Table 2: Devices covered by this letter and for which GMED SAS is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name and/or Basic UDI-DI (under MDR application)	Risk class of the device according to Annex VIII of Regulation (EU) 2017/745	Identification of the device certified under Directive 90/385/EEC or 93/42/EEC and intended to be substituted, if applicable	Reference(s) of the certificate(s) under Directive 90/385/EEC or 93/42/EEC*
N/A	N/A	N/A	N/A

**Historique de révision de la lettre**  
**Confirmation Letter Revision History**

Date	Révision/Revision	Action
26/10/2023	39453 rev. 0	Première émission <i>Initial issuance</i>
28/02/2024	39453 rev. 1	Ajout de dispositifs suite à demande formelle de certification <i>Addition of devices further to the Formal Application for certification</i>

Pour toute question concernant le statut ou la validité de cette lettre, veuillez contacter : [g-med-certificats@lne-gmed.com](mailto:g-med-certificats@lne-gmed.com)

For any query about the status of validity of this letter, please contact : [g-med-certificats@lne-gmed.com](mailto:g-med-certificats@lne-gmed.com)