2023/607/EU SELF-DECLARATION

To whom it may concern

We,

Overfibers S.r.l.
Via Malatesta, 7 40026 Imola (BO), Italy
Vat number 01723440382
+39 0542 52153/info@overfibers.com

hereby declare that the products listed in ANNEX I of this self-declaration are in scope of the European Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices by complying with the following requirements:

a) Devices continue to comply with Directive 93/42/EEC,

b) There are no significant changes in design and intended purpose,

c) Devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health,

d) No later than May 26th 2024, the manufacturer has put in a QMS in accordance with EU MDR,

e) No later than May 26th 2024, the manufacturer has lodged a formal application with a notified body, and, no later than September 26th 2024, the notified body and the manufacturer have signed a written agreement in accordance with EU MDR.

(NB Confirmation Letter attached in ANNEX II)

Therefore, the EC Certificate attached in ANNEX III is considered as valid until December 31st 2028.

Yours Sincerely,
Imola, 02/05/2024

Overfibers S.r.l.
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40026 Imola (BO)
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Fax +39.0542.1900078
P.IVA e C.F. 01723440382
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Castrenze Genovese

President

ANNEX I – According to MDD Extension, the devices for the continued placing on the market

Notified Body	ICIM S.p.A.		
Date of Extension Agreement	December 21st, 2023		
Expiration Date of Extension	December 31st, 2028		
Standard(s)	MDD 93/42/EEC		
Extension Reason	To maintain the MDD Certificate while MDR Audit is not completed		
Contact Information of NB	+39 02 725341 / info@icim.it		
Contact Address of NB	Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)		
Devices Name	• Cements for dental use 1. OverCEM SA Universal 2. OverCEM SA Translucent 3. OverCEM SA Opaque 4. OverCEM Ti-Abutment • Endodontic Posts 5. Hi-Rem Post 5a - Hi-Rem Polygon Post 5b - Hi-Rem Prosthetic Post 5c - Hi-Rem Endodontic Post 6. Over Post 6a - Polygon Over Post 6b - Prosthetic Over Post 6c - Endodontic Over Post 6d - Cylindrical Over Post 6e - Conical Over Post 6f - Duo Over Post 6g - Cylindrical Over Post Black 6h - Conical Over Post Black 7. Hi-Rem+ 8. Over Post+ • Endodontic Reamers 9. Drill 9a - Polygon Drill 9b - Prosthetic Drill 9c - H-Endodontic Drill 9d - Endodontic Drill 9e - Cylindrical Drill 9f - Conical Drill	**MDR Classification**	Class IIa
MDD Certificate Reference	EC Certificate 0425-M ED-004006-00		

Note: Certificate 0425-M ED-004006-00 was originally expired on May 26th 2024 and now it is under the MDD certification Extension Agreement provided by ICIM S.p.A. in December 21st 2023, the transition timeline 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 December 31st 2028.

ANNEX II – NB Confirmation Letter

OVERFIBERS srl
Via Malatesta, 7
40026 IMOLA (BO)

2023, December 21st

Notified Body Confirmation Letter
Reference: 139673/23

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:

OVERFIBERS srl
Via Malatesta, 7
40026 IMOLA (BO)
Italy
SRN number: IT-MF-000037545

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
Identificazione su NANDO CE0425

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
Cement for dental use	IIa	N/A	EC Certificate - ICIM N° 0425-MED-004006-00 NB 0425
Endodontic reamers	IIa	N/A	EC Certificate - ICIM N° 0425-MED-004006-00 NB 0425
Endodontic posts	IIa	N/A	EC Certificate - ICIM N° 0425-MED-004006-00 NB 0425

Table 2: Devices covered by this letter and for which the NB 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
2023/12/21	01	Initial issue

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

Dott. Edoardo Dossena
Product Sales Manager Product Certification,
Inspections and Directives
ICIM S.p.A.

Dott. Dario Bruno
Sales Director
ICIM S.p.A.

ANNEX III – EC Certificate

CE
0425

ICIM

Il presente documento annulla e sostituisce il certificato di pari numero emesso in data 29/04/2021.

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

Certificato N. / *Certificate No.* **0425-MED-004006-00**

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)

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:

OVERFIBERS S.R.L.

Sede Legale e Operativa
Via Malatesta, 7 - 40026 Imola (BO)
Italia

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

Cemento ad uso odontoiatrico / *Cement for dental use*
Frese endodontiche / Endodontic reamers
Perni endodontici / Endodontic posts

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*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
18/06/2020	**25/05/2021**	**26/05/2024**

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ICIM S.p.A. - Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)