June 2023

Notified Body Confirmation Letter

Reference: NBCL0038.01

Re: US Endodontics, LLC
Endodontic Rotary Files
NSAI File Number 745.074

HEAD OFFICE

1 Swift Square,
Northwood, Santry,
Dublin 9, Ireland
T +353 (0)1 807 3800
F +353 (0)1 807 3844
E certification@nsai.ie

NSAI.ie

REGIONAL CENTRE

Limerick
Plassey Park Road
Castletroy, Limerick

1 Swift Square,
Northwood, Santry,
Dublin 9, Ireland
T +353 61 330 708
F +353 61 330 698

INTERNATIONAL OFFICE

NSAI Inc.
20 Trafalgar Square
Suite 603
Nashua, NH 03063

T +1 603 882 4412
F +1 603 882 1985

NSAIinc.com

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 National Standards Authority of Ireland (NSAI), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0050 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:

US Endodontics, LLC
2809 W. Walnut Street
Johnson City
TN 37604, USA
SRN Number : Not yet available

The devices covered by the formal application and the written agreement mentioned above are identified in the Table 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Seán O Callaghan
European Medical Device Operations Manager
Medical Devices, NSAI

Dr Majella Geraghty
European Medical Device Operations Manager
Medical Devices, NSAI

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Suite 603
Nashua, NH 03063

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F +1 603 882 1985

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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
EdgeFile XR	IIa	n/a	252.1114 0050
EdgeFile X1	IIa	n/a	252.1114 0050
EdgeFile X3	IIa	n/a	252.1114 0050
EdgeFile X5	IIa	n/a	252.1114 0050
EdgeFile X7	IIa	n/a	252.1114 0050
EdgeGlidePath	IIa	n/a	252.1114 0050
EdgeOne Fire	IIa	n/a	252.1114 0050
EdgeOne Fire Glidepath	IIa	n/a	252.1114 0050
EdgeSequel Sapphire	IIa	n/a	252.1114 0050
EdgeOne Platinum	IIa	n/a	252.1114 0050
EdgeTaper	IIa	n/a	252.1114 0050
EdgeTaper Platinum	IIa	n/a	252.1114 0050

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
n/a	n/a	n/a	n/a

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023.06.27	NBCL0038.01	Initial issue

Certificate of Registration of Quality Management System to ISO 13485:2016

Australia - Therapeutic Goods (Medical Devices) Regulations, 2002,
☒ Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure.
Canada - Medical Devices Regulations – Part 1- SOR 98/282
Japan- MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (,as applicable)
United States - 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,
☒ 21 CFR 820 – Quality System Regulation,

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

US Endodontics, LLC
2809 W. Walnut St.
Johnson City, TN 37604
USA

Facility ID: F002759
has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

The Design, Manufacture, Contract Manufacturing, and Distribution of Endodontic Obturators, Verifiers, Sterile and Non-sterile Dental Rotary Files.

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.4830 / Rev 3
Certification Granted: 2019/10/02
Effective Date: 2023/10/02
Expiry Date: 2025/10/01

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800
National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412
All valid certifications are listed on NSAI's website – www.nsaiinc.com The continued validity of this certificate may be verified under "Approved Client Listing