ANDERSEN CALEDONIA

Caledonian House, Phoenix Crescent, Strathclyde Business Park, Bellshill, Lanarkshire, ML4 3NJ
Tel: 01698 844476 Fax: 01698 844481 Email: regulatory@andersencaledonia.co.uk

19th July 2023

To whom it may concern

Andersen Caledonia have received an extension to their Medical Device Directive (MDD) 93/42/EEC certification (Certificate number GB19/964735). See attached letter from SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO.

While Andersen Caledonia continue to transition to the EU MDR 2017/745, this letter allows us to release the device listed in the attached letter and MDD certificate, to the market.

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

• 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

Further updates will be provided, if there are any changes to the certification held by Andersen Caledonia.

Kind Regards

QA and RA Team
Andersen Caledonia

Andersen Caledonia
Caledonian House,
Phoenix Crescent,
Strathclyde Business Park
Bellshill, ML4 3NJ
UK

29/06/2023

Confirmation Letter Reference: CLNB1639 GBPC6743

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement 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, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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:

Andersen Caledonia
Caledonian House,
Phoenix Crescent,
Strathclyde Business Park
Bellshill, ML4 3NJ
UK

Authorised representative:
International Associates Auditing & Certification Limited Ireland
The Black Church
St Mary's Place
Dublin 7
D07 P4AX
Ireland
SRN: GB-MF-000030234

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or

Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 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 SGS Belgium NV 1639,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / 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
Sterile Single Use Surgical Instruments and Supplementary Devices: Sterile Surgical Scissors, 5060544340241	Class IIa	N/A	GB19/964735; NB1639

Device name / 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
Sterile Surgical Retractors, 5060544340258 Sterile Surgical Grasping Forceps, 5060544340265 Sterile Surgical Dissecting Forceps, 5060544340272 Sterile Surgical Suction Tubes, 5060544340289 Sterile Surgical Trocar & Cannula for Hormone Implant, 5060544340296 Sterile Surgical Curettes, 5060544340302 Sterile Surgical Hooks, 5060544340319 Sterile Surgical Vasectomy Forceps, 5060544340326 SPY712 Intravitreal Delivery Guide 5060544340005 Sterile Surgical Clamps, 5060544340357 Sterile Surgical Dissectors. 5060544340364 Sterile Orthodontic Devices: Dental/Oral Wires, Eyelet Wires, Tie Wires and Snare Wires. 5060544340333 5060544340340			
Sterile Dressing Scissors, 5060544340074 Sterile Needle Holders, 5060544340081	Class Is	N/A	GB19/964735; NB1639

Device name / 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
Sterile Scalpel Handles, 5060544340098 Sterile Dilators, 5060544340104 Sterile Dental Syringe without Needle for use with re-filled Cartridges, 5060544340111 Sterile Grasping Forceps, 5060544340128 Sterile Probes, 5060544340135 Sterile Clamps, 5060544340142 Sterile Hooks, 5060544340159 Sterile Speculum, 5060544340166 Sterile Podiatry Instruments. 5060544340173 Sterile Drapes, 5060544340180 Sterile Gauze swabs, 5060544340197 Sterile Spatulas Sterile Depressors 5060544340203 Sterile Quivers. 5060544340210 Sterile Surgical Gowns Sterile 5060544340227 Nasal Swabs Sterile 5060544340234 Sterile procedure packs in accordance with article 12 of the medical device directive 5060544340371			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/06/29	Version 1	Initial issue
2023/07/12	Version 2	Addition of device SPY712 Intravitreal Delivery Guide and Sterile procedure packs, which was omitted in the initial issue of the Confirmation Letter.

EC Certificate Production Quality Assurance System: Certificate GB19/964735

The management system of

Andersen Caledonia Limited

Caledonian House, Phoenix Crescent, Strathclyde Business Park,
Lanarkshire, ML4 3NJ, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 01 March 2021until 19 January 2023
and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 18 January 1999

Certification is based on reports numbered GB/PC/ 08642

Authorised by

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639

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Andersen Caledonia Limited

Directive 93/42/EEC

on medical devices, Annex V

Issue 6

Detailed scope

Sterile Single Use Surgical Instruments and Supplementary Devices:

Sterile Surgical Scissors, Sterile Surgical Retractors, Sterile Surgical Grasping Forceps, Sterile Surgical Dissecting Forceps, Sterile Surgical Suction Tubes, Sterile Surgical Trocar & Cannula for Hormone Implant, Sterile Surgical Curettes, Sterile Surgical Hooks, Sterile Surgical Vasectomy Forceps, Sterile Surgical SPY712 Intravitreal Delivery Guide, Sterile Surgical Clamps, Sterile Surgical Dissectors.

Sterile Orthodontic Devices:

Dental/Oral Wires, Eyelet Wires, Tie Wires and Snare Wires.

Class 1 sterile -Sterility Aspects Only -Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Single Use Non Invasive or Body Orifice Invasive, Medical Instruments and Supplementary Devices:

Sterile Dressing Scissors, Sterile Needle Holders, Sterile Scalpel Handles, Sterile Dilators, Sterile Dental Syringe without Needle for use with re-filled Cartridges, Sterile Grasping Forceps, Sterile Probes, Sterile Clamps, Sterile Hooks, Sterile Speculum, Sterile Podiatry Instruments. Sterile Drapes, Sterile Gauze swabs, Sterile Spatulas and Sterile Depressors Sterile Quivers.
Sterile Surgical Gowns
Sterile Nasal Swabs

Sterile procedure packs in accordance with article 12 of the medical device directive

Where the above scope includes Class IIb or Class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in Addition to this certificate to place the device on the market.