AngioDynamics, Inc.
603 Queensbury Avenue
Queensbury
New York
12804
USA

18 July 2023

Notified Body Confirmation Letter
Reference: EU2023-607/631819

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

AngioDynamics, Inc
603 Queensbury Avenue
Queensbury
New York
12804
USA

SRN Number (if available): US-MF-000001155

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 BSI Group The Netherlands B.V.,

Firmato digitalmente da Donatella Allemand
Data: 2023.07.18 16:02:35 +02'00'

Donatella Allemand
BSI Scheme Manager

Digitally signed by Elizabeth Champagne
Date: 2023.07.18 11:42:11 -05'00'

Elizabeth Champagne
BSI Scheme Manager

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
505168401657	Class III	Xcela Power Injectable PICC	CE 622285; NB 2797 CE 622294; NB 2797
505168401657	Class III	Xcela PICC with PASV Valve Technology Xcela Hybrid PICC with PASV Valve Technology	CE 622285; NB 2797 CE 622296; NB 2797
505168401657	Class III	BioFlo™ PICC with ENDEXO™ Technology	CE 622285; NB 2797 CE 622297; NB 2797
505168401657	Class III	BioFlo™ PICC with ENDEXO™ and PASV™ Valve Technology BioFlo™ Hybrid PICC with ENDEXO™ and PASV™ Valve Technology	CE 622285; NB 2797 CE 622299; NB 2797
50516840204W	Class III	BioFlo DuraMax with Endexo Technology Chronic Hemodialysis Catheter and accessories	CE 622285; NB 2797 CE 623831; NB 2797
50516840185B	Class IIb excluding Class IIb implantable non-WET	Peripheral Vascular Catheters: BioFlo Midline Catheters	CE 622285; NB 2797
50516840214Y	Class III	SmartPort, LifePort and Vortex Implantable Infusion Ports	CE 579476; NB 2797 CE 94770; NB 2797
505168402252	Class III	AngioVac Cannula	CE 579476; NB 2797 CE 579481; NB 2797
50516840024U	Class III	Smart Port + and Smart Port Plastic Implantable Infusion Port System	CE 579476; NB 2797 CE 710722; NB 2797
505168402456	Class IIb excluding Class IIb implantable non-WET	Medical Microwave Equipment and Applicators: Solero Microwave Applicators and Generators	CE 579476; NB 2797

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
50516840275C	Class IIb excluding Class IIb implantable non-WET	RFA Surgical Systems – Starburst, Talon, Habib, and Uniblate Electrosurgical Probes	CE 579476; NB 2797
50516840285E	Class IIb excluding Class IIb implantable non-WET	RFA Surgical Systems – Dispersive Pads/Thermo Pads for RFA applications	CE 579476; NB 2797
50516840124X	Class IIb excluding Class IIb implantable non-WET	Infusion Sets and Needles: Lifeguard and LifePort Sterile Infusion Sets	CE 579476; NB 2797
505168402354	Class IIa	Cardiopulmonary Bypass Circuits: AngioVac Circuit	CE 579476; NB 2797
50516840265A	Class IIa	RF Surgical Systems – RITA Starburst Access Systems (Hard Introducers)	CE 579476; NB 2797

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	Action
2023/07/18	Initial issue