Philips Image Guided Therapy Corporation
9965 Federal Drive
Colorado Springs, Colorado
80921
USA

December 14, 2023

Notified Body Confirmation Letter

Reference: EU2023-607/672713

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:

Philips Image Guided Therapy Corporation
9965 Federal Drive
Colorado Springs, Colorado
80921
USA
SRN Number (if available): US-MF-000018632

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

[redacted]

Luis Martinez

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
Refinity ST Rotational IVUS Catheter	Class III	N/A	CE 742145; NB 2797 CE 742150; NB 2797
Eagle Eye Platinum RX Digital IVUS Catheter	Class III	N/A	CE 742145; NB 2797 CE 742147; NB 2797
Eagle Eye Platinum ST RX Digital IVUS Catheter	Class III	N/A	CE 742145; NB 2797 CE 742147; NB 2797
Lead Locking Device (LLD, LLD 1, LLD 2, LLD 3, LLD E, LLD EZ, LLD Accessory Kit, Lead Cutter)	Class IIa	N/A	CE 550209; NB 2797
Visions PV .018 Digital IVUS Catheter	Class IIa	N/A	CE 742145; NB 2797
Reconnaissance PV .018 OTW Digital IVUS Catheter	Class IIa	N/A	CE 742145; NB 2797
Visions PV .014P RX Digital IVUS Catheter	Class IIa	N/A	CE 742145; NB 2797 CE 742147; NB 2797
Omniwire Pressure Guide Wire	Class III	N/A	CE 742145; NB 2797 CE 735820; NB 2797
GlideLight Laser Sheath	Class III	N/A	CE 550209; NB 2797 CE 554849; NB 2797
AngioSculpt PTA Scoring Balloon Catheter	Class IIa	N/A	CE 632473; NB 2797
TightRail, TightRail Sub-C Rotating Dilator Sheaths	Class III	N/A	CE 550209; NB 2797 CE 611679; NB 2797
Turbo-Elite Laser Atherectomy Catheter	Class IIa	N/A	CE 550209; NB 2797
Bridge Occlusion Balloon Catheter	Class III	N/A	CE 550209; NB 2797 CE 650647; NB 2797
ELCA Coronary Laser Atherectomy Catheter	Class III	N/A	CE 550209; NB 2797 CE 554813; 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
Turbo-Power Laser Atherectomy Catheter	Class IIb excluding Class IIb implantable non-WET	N/A	CE 550209; NB 2797
IntraSight System	Class IIa	N/A	CE 742145; NB 2797
IntraSight Mobile	Class IIa	N/A	CE 742145; NB 2797
Philips Laser System	Class IIb excluding Class IIb implantable non-WET	N/A	CE 550209; NB 2797
SyncVision System	Class IIa	N/A	CE 742145; NB 2797
Sterile Equipment Covers	Class I device placed on the market in sterile condition	N/A	CE 742148; NB 2797
Tack Endovascular System	Class IIb implantable non-WET	N/A	CE 621167; NB 2797
Visions PV .035 Digital IVUS Catheter	Class III	N/A	CE 742145; NB 2797 CE 742557; 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
2023/12/14	Initial issue