ICU Medical Inc.
951 Calle Amanecer
San Clemente, CA 92673
USA

18 October 2024

Notified Body Confirmation Letter
Reference: EU2023-607/849480

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:

ICU Medical Inc.
951 Calle Amanecer
San Clemente, CA 92673
USA

SRN Number (if available): US-MF-000009764

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Graeme Tunbridge
Senior Vice President, Medical Devices

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
Jelco Needle Protection Point-Lok	Class I device placed on the market in sterile condition	N/A	CE 685113, NB #2797
Portex LOCKIT Plus Regional Anaesthesia Catheter Securement Device	Class I device placed on the market in sterile condition	N/A	CE 685113, NB #2797
Portex Catheter Connector Key	Class I device placed on the market in sterile condition	N/A	CE 685113, NB #2797
Portex Tracheal Intubation Stylet	Class I device placed on the market in sterile condition	N/A	CE 685113, NB #2797
Portex Extra Long Stylet for Tracheal Tube	Class I device placed on the market in sterile condition	N/A	CE 685113, NB #2797
Portex® Single Use Exchange Guide	Class I device placed on the market in sterile condition	N/A	CE 685113, NB #2797
Portex® Single Use Bougie Coudé Tip	Class I device placed on the market in sterile condition	N/A	CE 685113, NB #2797
Portex® Tracheal Tube Guide	Class I device placed on the market in sterile condition	N/A	CE 685113, NB #2797
Nasopharyngeal Tubes	Class I device placed on the market in sterile condition	N/A	CE 685113, NB #2797
Portex® Acapella® Vibratory PEP Therapy System	Class IIa	N/A	G1 097063 0012, NB #0123
Portex® Acapella® Choice Vibratory PEP Device.	Class IIa	N/A	G1 097063 0012, NB #0123
HD CliniFlo Spirometer	Class IIa	N/A	G1 097063 0012, NB #0123
Coach2 Incentive Spirometer	Class IIa	N/A	G1 097063 0012, NB #0123
Portex Tracheal Tubes	Class IIa	N/A	G1 097063 0011, NB #0123
Critical Care Catheters, **- Advanced Sensor Catheters (TriOx/TDM)**	Class III	N/A	252.129, NB #0050
Critical Care Catheters, **- Central Venous Catheters**	Class III	N/A	252.129, NB #0050

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
Critical Care Catheters, **- Central Venous Oximetry Catheters (TriOx/CVOC)**	Class III	N/A	252.129, NB #0050
Critical Care Catheters, **- Thermodilution (TD) Catheters**	Class III	N/A	252.129, NB #0050
Tego Connector	Class IIa	N/A	252.631, NB #0050
Disinfecting Caps: SwabCap	Class IIa	N/A	252.998, NB #0050
Administration sets	Class IIa	N/A	252.602, NB #0050
Extension sets	Class IIa	N/A	252.602, NB #0050
Bag Spikes	Class IIa	N/A	252.602, NB #0050
Stopcocks and Manifolds	Class IIa	N/A	252.602, NB #0050
Neutron Connector	Class IIa	N/A	252.602, NB #0050
Clave Needlefree Connectors	Class IIa	N/A	252.602, NB #0050
Nuitiv Connector	Class IIa	N/A	252.602, NB #0050
Administration/Extension Kits	Class IIa	N/A	252.602, NB #0050
Transfer Sets	Class IIa	N/A	252.602, NB #0050
Closed System Transfer Devices: ChemoClave	Class I device placed on the market in sterile condition	N/A	252.602, NB #0050 252.1002, NB #0050
Closed System Transfer Devices: ChemoLock	Class I device placed on the market in sterile condition	N/A	252.602, NB #0050 252.1002, NB #0050
Closed System Transfer Devices: Spiros	Class I device placed on the market in sterile condition	N/A	252.714, NB #0050 252.602, NB #0050
Vented and Non Vented Vial Adapters	Class I device placed on the market in sterile condition	N/A	252.1002, NB #0050
Vented and Non Vented Vial Adapters with Clave Connector	Class I device placed on the market in sterile condition	N/A	252.1002, NB #0050
ChemoClave Closed Vial Adapters	Class I device placed on the market in sterile condition	N/A	252.1002, NB #0050
Accudynamic	Class IIa	N/A	252.702, NB #0050

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
Basic Monitoring Set Devices (Pressure Tubing, Flushes, Stopcocks, Extension Sets, Luers/ Caps/ Connectors/ Valves)	Class IIa	N/A	252.702, NB #0050
SafeSet Kits	Class IIa	N/A	252.702, NB #0050
Cardiac Catheriation Kits	Class IIa	N/A	252.702, NB #0050
Transducer Monitoring Kits	Class IIb excluding Class IIb implantable non-WET	N/A	252.702, NB #0050
Intracranial Transducer Monitoring Kits	Class IIb excluding Class IIb implantable non-WET	N/A	252.702, NB #0050
Transducer SafeSet Kits	Class IIb excluding Class IIb implantable non-WET	N/A	252.702, NB #0050
Transducer Cardiac Catherisation Kits	Class IIb excluding Class IIb implantable non-WET	N/A	252.702, NB #0050
Thermoset injectate delivery system	Class IIa	N/A	252.702, NB #0050
NRFit Cap	Class I device placed on the market in sterile condition	N/A	CE 669121, NB #2797
Portex Loss of Resistance (L.O.R.) Syringe with NRFit Connector	Class I device placed on the market in sterile condition	N/A	CE 669121, NB #2797
CADD-Solis VIP Ambulatory Infusion Pump	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
CADD-Solis Ambulatory Infusion Pump - HPCA	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
PharmGuard Administrator Medication Safety Software (MSS)	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
CADD Administration Sets	Class IIa	N/A	CE 669121, NB #2797
CADD High Volume Administration Sets	Class IIa	N/A	CE 669121, NB #2797
CADD Yellow High Volume Administration Sets with NRFit connector	Class IIa	N/A	CE 669121, 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
CADD Extension Set	Class IIa	N/A	CE 669121, NB #2797
CADD Medication Cassette Reservoir	Class IIa	N/A	CE 669121, NB #2797
CADD Bag Spike Set	Class IIa	N/A	CE 669121, NB #2797
CADD Filling Adapter	Class I device placed on the market in sterile condition	N/A	CE 669121, NB #2797
CADD Infusion Adapter	Class IIa	N/A	CE 669121, NB #2797
Jelco Blood Draw Hypodermic Needle-Pro	Class IIa	N/A	CE 669121, NB #2797
Jelco Hypodermic Needle-Pro Needles	Class IIa	N/A	CE 669121, NB #2797
Jelco Hypodermic Needle-Pro with Syringe Needles	Class IIa	N/A	CE 669121, NB #2797
Hypodermic Needle-Pro Fixed Needle Insulin Syringe	Class IIa	N/A	CE 669121, NB #2797
Insulin Syringe with Jelco Hypodermic Needle-Pro Edge	Class IIa	N/A	CE 669121, NB #2797
Jelco Hypodermic Needle-Pro Edge	Class IIa	N/A	CE 669121, NB #2797
Jelco Hypodermic Needle-Pro Edge with Syringe	Class IIa	N/A	CE 669121, NB #2797
Port-A-Cath Subcutaneous Tunneling Tool	Class IIa	N/A	CE 669121, NB #2797
Deltec Peel-Away Introducer Set	Class III	N/A	CE 669121, NB #2797
Deltec Port-A-Cath Needles Plastic Hub	Class IIa	N/A	CE 669121, NB #2797
Deltec Gripper Power P.A.C. Plus Non-Coring Needles	Class IIa	N/A	CE 669121, NB #2797
Deltec Gripper Micro Non-Coring Needles	Class IIa	N/A	CE 669121, NB #2797
Deltec Gripper Plus Non-Coring Needles	Class IIa	N/A	CE 669121, 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
Deltec Gripper Non-Coring Needles	Class IIa	N/A	CE 669121, NB #2797
Port-A-Cath Implantable Access Systems - Deltec P.A.S Ports	Class III	N/A	CE 669121, NB #2797 CE 669193, NB #2797
Port-A-Cath Implantable Access Systems - Deltec Port-A-Cath & Port-A-Cath II Ports	Class III	N/A	CE 669121, NB #2797 CE 669193, NB #2797
Port-A-Cath Implantable Access Systems - Deltec ProPort Ports	Class III	N/A	CE 669121, NB #2797 CE 669193, NB #2797
Port-A-Cath Implantable Access Systems - Deltec Port-A-Cath II P.A.C. Dual-Lumen	Class III	N/A	CE 669121, NB #2797 CE 669193, NB #2797
Port-A-Cath Implantable Access Systems - Deltec Port-A-Cath II Power P.A.C. Dual-Lumen	Class III	N/A	CE 669121, NB #2797 CE 669193, NB #2797
Port-A-Cath Implantable Access Systems - Deltec Port-A-Cath Power P.A.C.	Class III	N/A	CE 669121, NB #2797 CE 669193, NB #2797
Port-a-Cath Implantable Access Systems - Epidural and Intraspinal	Class III	N/A	CE 669121, NB #2797 CE 669193, NB #2797
Jelco Safety ProtectIV Catheters	Class IIa	N/A	CE 669121, NB #2797
ViaValve ViaValve -W Safety I.V. Catheters	Class IIa	N/A	CE 669121, NB #2797
Jelco Conventional Cathlon IV Catheters	Class IIa	N/A	CE 669121, NB #2797
Jelco Radiopaque I.V. Catheters	Class IIa	N/A	CE 669121, NB #2797
Jelco Optiva Radiopaque I.V. Catheters	Class IIa	N/A	CE 669121, NB #2797
Jelco Conventional Optiva 2 Radiopaque IV Catheters	Class IIa	N/A	CE 669121, NB #2797
Jelco Conventional Jelco Clear IV Catheters	Class IIa	N/A	CE 669121, 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
Jelco Conventional Optiva Winged IV Catheters	Class IIa	N/A	CE 669121, NB #2797
Jelco Conventional Jelco Radiopaque IV Catheters	Class IIa	N/A	CE 669121, NB #2797
Jelco Conventional Optiva IV Catheters	Class IIa	N/A	CE 669121, NB #2797
Jelco Conventional Plus IV Catheters	Class IIa	N/A	CE 669121, NB #2797
Jelco Convention Jelco 2 IV Catheter	Class IIa	N/A	CE 669121, NB #2797
Portex ABS Liquid Heparin	Class IIa	N/A	CE 669121, NB #2797
Portex ABS Dry Heparin - With Needle	Class IIa	N/A	CE 669121, NB #2797
Cleo 90 Infusion Set	Class IIa	N/A	CE 669121, NB #2797
EchoGlo Peripheral Nerve Block Needle: Continuous System	Class IIa	N/A	CE 669121, NB #2797
EchoGlo Peripheral Nerve Block Needle: Single Shot	Class IIa	N/A	CE 669121, NB #2797
Portex Epidural Tuohy and Hustead Needles with NRFit Connector	Class IIa	N/A	CE 669121, NB #2797
Portex Epidural Flat Filter with NRFit Connector	Class IIa	N/A	CE 669121, NB #2797
EpiFuse Catheter Connector with NRFit Connector and Key	Class IIa	N/A	CE 669121, NB #2797
Portex Epidural Minipack with NRFit Connector	Class IIa	N/A	CE 669121, NB #2797
Portex Epidural Catheter Kit with NRFit Connector	Class IIa	N/A	CE 669121, NB #2797
Portex Epidural Single Shot Trays	Class IIa	N/A	CE 669121, NB #2797
Hotline Fluid Warming Sets	Class IIa	N/A	CE 669121, NB #2797
Hotline Routine Fluid Warmer	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, 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
Level 1® Convective Warmer	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Level 1 Neo-Therm Skin Temperature Sensor	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Level 1 Tympanic Temperature Sensor	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Level 1 Esophageal/Rectal Temperature Probes	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Level 1 Skin Temperature Sensor	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Portex Flex Tubes	Class IIa	N/A	CE 669121, NB #2797
Portex Thermovent O2	Class IIa	N/A	CE 669121, NB #2797
Portex Thermovent T Heat & Moisture Exchanger	Class IIa	N/A	CE 669121, NB #2797
Portex Thermovent T2 Heat & Moisture Exchanger with Oxygen & Suction Port	Class IIa	N/A	CE 669121, NB #2797
Portex Thermovent 600/1200 Heat & Moisture Exchangers	Class IIa	N/A	CE 669121, NB #2797
Portex Filtered Heat & Moisture Exchangers	Class IIa	N/A	CE 669121, NB #2797
Portex Heat & Moisture Exchangers	Class IIa	N/A	CE 669121, NB #2797
BLUselect Tracheostomy Tubes	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
BLUselect Suctionaid Tracheostomy Tubes	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
BLUselect Inner Cannula	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
BLUgriggs Percutaneous Dilation Tracheostomy Procedural Kit with BLUselect Tracheostomy Tube	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
BLUperc Percutaneous Dilation Tracheostomy Procedural Kit with or	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, 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
without BLUselect Tracheostomy Tube			
EzPAP Positive Airway Pressure Therapy Device with Mask	Class IIa	N/A	CE 669121, NB #2797
EzPAP Positive Airway Pressure Therapy Device with Mouthpiece	Class IIa	N/A	CE 669121, NB #2797
Portex ACE MDI Spacers	Class IIa	N/A	CE 669121, NB #2797
Portex ACE Kits with Masks	Class IIa	N/A	CE 669121, NB #2797
Bivona Custom Tracheostomy Tube	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Bivona Neonatal/Pediatric Hyperflex Uncuffed Adjustable Tracheostomy Tube	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Bivona Neonatal/Pediatric Uncuffed Tracheostomy Tube	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Bivona Neonatal/Pediatric TTS Tracheostomy Tube	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Bivona Neonatal/Pediatric Flextend TTS Tracheostomy Tube	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Bivona Cuffless Tracheostomy Tube	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Bivona Tracheostomy Tube	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Bivona Inner Cannula	Class IIa	N/A	CE 669121, NB #2797
Pneupac paraPAC Plus Disposable CPAP Circuit	Class IIa	N/A	CE 669121, NB #2797
paraPAC plus ventilator	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Single Limb Circuits for Pneupac DEMAND type Ventilators	Class IIa	N/A	CE 669121, 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
Single Limb Circuit for Pneupac paraPAC plus Ventilator	Class IIa	N/A	CE 669121, NB #2797
Portex Swivel Connector	Class IIa	N/A	CE 669121, NB #2797
Portex 15mm Double Swivel Connector	Class IIa	N/A	CE 669121, NB #2797
Portex Catheter Mount	Class IIa	N/A	CE 669121, NB #2797
Hotline Gas Vent	Class IIa	N/A	CE 669121, NB #2797
Hotline Connector Extension	Class IIa	N/A	CE 669121, NB #2797
Portex® Replacement Inner Cannula for UniPerc® Adjustable Flange Tracheostomy Tube	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Portex UniPerc™ Percutaneous Dilation Tracheostomy Kit	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Portex UniPerc™ Adjustable Flange Tracheostomy Tube	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Replacement Guidewire for UniPerc™ Percutaneous Dilation Tracheostomy Kit	Class IIa	N/A	CE 669121, NB #2797
LogiCal Pressure Monitoring Kits	Class IIa	N/A	CE 669121, NB #2797
LogiCal Pressure Monitoring Extension Line	Class IIa	N/A	CE 669121, NB #2797
LogiCal Closed Blood Sampling Systems	Class IIa	N/A	CE 669121, NB #2797
LogiCal Pressure Monitoring Transducer	Class IIb excluding Class IIb implantable non-WET	N/A	CE 669121, NB #2797
Portex Blue-Line SACETT Suction above the cuff Tracheal Tube	Class IIa	N/A	CE 669121, NB #2797
Portex Cole Neonatal Tube	Class IIa	N/A	CE 669121, 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
Portex Cut to Length Tracheal Tube	Class IIa	N/A	CE 669121, NB #2797
Portex Neonatal/Pediatric Endotracheal tube and 15mm connector with sideport	Class IIa	N/A	CE 669121, NB #2797
Portex Neonatal/Pediatric Intubation Kit	Class IIa	N/A	CE 669121, NB #2797
Portex siliconised tracheal tube with tube holder	Class IIa	N/A	CE 669121, NB #2797
Portex Polar Preformed Tracheal Tubes	Class IIa	N/A	CE 669121, NB #2797
Portex Reusable Reinforced Silicone Rubber Tracheal Tubes	Class IIa	N/A	CE 669121, NB #2797
Portex single use reinforced Tracheal Tubes	Class IIa	N/A	CE 669121, NB #2797
Portex Tracheal Tubes	Class IIa	N/A	CE 669121, NB #2797
Portex Breathing Filter	Class IIa	N/A	CE 669121, NB #2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
2024/07/17	Initial issue
2024/10/18	Updated to add all devices from NSAI and BSI and moved from Table 2 to Table 1