**Owen Mumford Limited**
Brook Hill, Woodstock
Oxfordshire
OX20 1TU
UK

20/05/2024

**Confirmation Letter Reference: CLNB1639 - GBPC 04459**

To whom it may concern,

Confirmation of receipt 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, 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:

**Owen Mumford Limited**
Brook Hill, Woodstock
Oxfordshire
OX20 1TU
UK
SRN: GB-MF-000021000

**Authorised Representative:**
Alte Häge 1
63762 Großostheim-Ringheim
Germany
SRN: MT-AR-000000234



The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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:

- 26th May 2026 for Class III custom-made implantable devices
- 31st 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)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st 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 NB1639,

Virginie SILORET
Global Medical Device Certification Manager
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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** | **MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage) | **MDD Device name** (please indicate if correlation with MDR denomination is not obvious) | 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 |
|---|---|---|---|---|
| Unistik 3 : Variant - Gentle, Comfort, Normal, Extra, Neonatal 7 Laboratory) 5016189UNISTIK3EF | Class IIa | Single use capillary blood sampling lancets<br><br>(Unistik 3 : Variant - Gentle, Comfort, Normal, Extra, Neonatal 7 Laboratory) | N/A | GB19/964726; NB1639 |
| Unistik Touch : Variants - Different sizes 5016189UNISTIKTOUCHKF | Class IIa | Contact activated safety lancets<br><br>(Unistik Touch : Variants - Different sizes) | N/A | GB19/964726; NB1639 |
| Unistik Heelstik : Variants - Different sizes 5016189UNISTIKHEELSTIK6R | Class IIa | Sterile single use healstick lancet<br><br>(Unistik Healstik : Variants - Different sizes) | N/A | GB19/964726; NB1639 |

| **Device name or Basic UDI-DI** | **MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage) | **MDD Device name** (please indicate if correlation with MDR denomination is not obvious) | 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 |
|---|---|---|---|---|
| Unistik TinyTouch : Variant - Preemie & Full Term 5016189UNISTIKTINYTOUCHHK | Class IIa | Sterile single use healstick lancet<br><br>(Unistik TinyTouch : Variant - Preemie & Full Term) | N/A | GB19/964726; NB1639 |
| Unifine Pentips (OM): Variants - Different sizes 5016189OMUNIFINEPENTIPSFN | Class IIa | Sterile Pen Needles<br><br>(Unifine Pentips (OM): Variants - Different sizes) | N/A | GB19/964726; NB1639 |
| Unifine Pentips Plus : Variants - Different sizes 5016189UNIFINEPENTIPS+LJ | Class IIa | Sterile Pen Needles<br><br>(Unifine Pentips Plus : Variants - Different sizes) | N/A | GB19/964726; NB1639 |
| Unifine Pentips (Pikdare) : Variants - Different sizes 5016189UNIFINEPENTIPS9B | Class IIa | Sterile Pen Needles<br><br>(Unifine Pentips (Pikdare) : Variants - | N/A | GB19/964726; NB1639 |

| **Device name or Basic UDI-DI** | **MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage) | **MDD Device name** (please indicate if correlation with MDR denomination is not obvious) | 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 |
|---|---|---|---|---|
| | | Different sizes) | | |
| Unifine SafeControl : Varaiants - Different sizes<br>5016189ATERIARG | Class IIa | Sterile safety pen needles<br><br>(Unifine SafeControl : Varaiants - Different sizes) | N/A | GB19/964726; NB1639 |
| TriCare : Variants - Different sizes<br>5016189TRICAREZD | Class IIa | Sterile Pen Needles<br><br>(TriCare : Variants - Different sizes) | N/A | GB19/964726; NB1639 |
| Unilet Lancets<br>5016189OMUNILETYA | Class IIa | Single use capillary blood sampling lancets<br><br>(Unilet Lancets) | N/A | GB19/964726; NB1639 |
| CSYNC Variants - EU + ROW; Germany<br>5016189CSYNCVK | Class IIa | Non-sterile auto-injection device.<br><br>(CSYNC Variants - EU + ROW; Germany) | N/A | GB19/964726; NB1639 |

| **Device name or Basic UDI-DI** | **MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage) | **MDD Device name** (please indicate if correlation with MDR denomination is not obvious) | 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 |
|---|---|---|---|---|
| Autoject 2 ; Variant - Fixed & Removable Needles 5016189AUTOJECT2JS | Class IIb | Non-sterile auto-injection device.<br><br>(Autoject 2 ; Variant - Fixed & Removable Needles) | N/A | GB19/964726; NB1639 |
| Ovaleap Pen 5016189OVALEAPXA | Class IIb | Pen injector for drug delivery<br><br>(Ovaleap Pen) | N/A | GB19/964726; NB1639 |
| Autopen 24 : Variants - Different Unit Volumes 5016189AUTOPEN24KL | Class IIb | Pen injector for drug delivery<br><br>(Autopen 24 : Variants - Different Unit Volumes) | N/A | GB19/964726; NB1639 |
| Autopen Classic : Variants - Different Unit Volumes 5016189AUTOPENYL | Class IIb | Pen injector for drug delivery<br><br>(Autopen Classic : Variants - Different Unit Volumes) | N/A | GB19/964726; NB1639 |

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 |
|---|---|---|
| 20/05/2024 | Version 1 | Initial issue |