Duckworth & Kent Ltd
Terence House
7 Marquis Business Centre
Royston Road
Baldock
Hertfordshire
SG7 6XL
UK

21/05/2024

Confirmation Letter Reference: CLNB1639 - GBPC 04406

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:

Duckworth & Kent Ltd
Terence House
7 Marquis Business Centre
Royston Road
Baldock
Hertfordshire
SG7 6XL
UK
SRN: GB-MF-000002176

Authorised Representative:
Emergo Europe
Westervoortsedijk 60
6827 AT Arnham
The Netherlands
SRN: NL-AR-000000116

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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,

Ian How
PP
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Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
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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
Irrigation & Aspiration IIa (Non-invasive) 50553138IrrAspR24U	Class IIa	Phaco range of irrigation and aspirating ophthalmic instrumentals	N/A	GB19/964587; NB1639
Irrigation & Aspiration IIa (Surgically Invasive) 50553138IrrAspR654	Class IIa	Phaco range of irrigation and aspirating ophthalmic instrumentals	N/A	GB19/964587; 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**
Forceps (Non-invasive) 50553138ForcepsR18V	Class I	N/A	MDD self-certified
Forceps (Invasive) 50553138ForcepsR595	Class I	N/A	MDD self-certified
Forceps (Surgically invasive) 50553138ForcepsR697	Class I	N/A	MDD self-certified

Hooks & Probes (Invasive) 50553138ProbesR5FR	Class I	N/A	MDD self-certified
Hooks & Probes (Non-invasive) 50553138ProbesR1FH	Class I	N/A	MDD self-certified
Hooks & Probes (Surgically invasive) 50553138ProbesR6FT	Class I	N/A	MDD self-certified
Irrigation & Aspiration Ir (Non-invasive) 50553138IrrAspR14S	Class I	N/A	MDD self-certified
Markers (Non-invasive) 50553138MarkersR19A	Class I	N/A	MDD self-certified
Markers (Invasive) 50553138MarkersR59J	Class I	N/A	MDD self-certified
Needle Holders (Non-invasive) 50553138NHoldersR1WD	Class I	N/A	MDD self-certified
Scissors (Surgically invasive) 50553138ScissorsR6UT	Class I	N/A	MDD self-certified
Speculum (Invasive) 50553138SpeculumR5SQ	Class I	N/A	MDD self-certified
Injectors (Surgically Invasive) 50553138InjectorsR637	Class I	N/A	MDD self-certified
Knives (Surgically Invasive) 50553138KnivesR6F6	Class I	N/A	MDD self-certified

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
21/05/2024	Version 1	Initial issue
04/07/2024	Version 2	Inclusion of Class I self-certified devices