Restorative Therapies Inc.
8098 Sandpiper Circle Suite M. Nottingham MD, 21236, United States of America

July 24, 2024

Confirmation Letter Reference: CLNB1639 - 607125

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, the 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:

Restorative Therapies Inc.
8098 Sandpiper Circle Suite M
Nottingham MD, 21236
United States of America
SRN Number (if available): US-MF-000023084

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
Netherlands

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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 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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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
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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**	**MDD Device name**	**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
Device 1 - RT300 M720XXXXXXXX0U The RT300 is a therapeutic device that exchanges energy in the form of functional electrical stimulation to the leg muscles; quadriceps, hamstrings, gluteals, tibialis anterior, and gastrocnemius, arm muscles; biceps, triceps, supraspinatus, deltoids, wrist flexors/extensors, and scapula stabilizers, or trunk muscles; abdominals, erector spinae.	IIa	Device 1 - RT300	N/A	Certificate # US19/819943556
Device 2 - Xcite Clinical Station M720FA2162180 The Xcite system is a therapeutic device that exchanges energy in the	IIa	Device 2 - Xcite Clinical Station	N/A	Certificate # US19/819943556

Device name or Basic UDI-DI	**MDR Device classification**	**MDD Device name**	**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
form of functional electrical stimulation to the leg muscles, arm muscles, or trunk muscles				

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-July-24	Version 1	Initial issue

Restorative Therapies Inc MDD Extension (DOC-823) Ver. 0

Approved By:

> **Ed Burkot** - Author
>
> January 22, 2025 6:46 PM GMT edd62fdb-7c0c-4e77-9938-6a4d9566b1c1

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