

Declaration of conformity system (Article 22)

We,

Dessintey Sas

Parc Technologique Metrotech Bâtiment 6

42650 Saint-Jean-Bonnefonds

France

Actor ID: FR-PR-000046298

Guarantee and declare, under our sole responsibility, that the medical device system:

SRT LAB, composed by:

- 1 Kiosk
- At least one of the following devices, up to a maximum total of 5 devices:
 - o SRT2
 - o SRT5
 - o SRT6

conforms with the requirements of this Regulation (EU) 2017/745 and the medical device system components are compatible with each other. The devices included in this system are intended to be used within the limits of use specified by their manufacturers. To create this system, we declare:

- have verified the compatibility of the devices and the other products and have carried out their activities in accordance with the instructions;
- have packaged the system and provided relevant information to users, including information to be provided by the manufacturers of other products that have been assembled;
- have subjected the combination of the devices and other products in the form of a system to appropriate internal control, verification and validation methods.

Intended purpose:

The main medical indications are the training of cognitive function and development of upper limb motricity

Basic UDI-DI Reference: 3770024593SRTLABDT

Common Specifications: N/A

Sterility: Not sterile

Conformity assessment procedure: N/A

Additional information: Technical File according DOCT-004-EN-Rev02

Place: Saint-Jean-Bonnefonds

Date: On January 29th, 2025

Name: M. Nicolas FOURNIER

Function: President

