EU Declaration of conformity

According Annex IV of Regulation (EU) 2017/745 on medical devices

We,

Dessintey Sas

Parc Technologique Metrotech Bâtiment 6
42650 Saint-Jean-Bonnefonds
France

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

IVS3 (V2)

Intensive Visual Simulation

is in conformity with the requirements of this Regulation (EU) 2017/745.

Class of device acc. Annex VIII of Regulation (EU) 2017/745:
Class I device with application of rule 11

Intended purpose:
The main medical indications are the treatment of upper limb deficits and neurological pain by means of modified visual feedback.

Manufacturer Single Registration Number (SRN): FR-MF-000009697

Basic UDI-DI Reference: 3770024593IVS33B

Common Specifications: N/A

Notified Body name and identification number: N/A

Notified Body certificate(s) reference: N/A

Conformity assessment procedure: N/A

Additional information: Technical File according DOCT-002-EN-Rev02

Place: Saint-Jean-Bonnefonds,
Date of emission: On December the 9th of 2022.
Date of initial declaration: On October the 1st of 2020

Name: M. Nicolas FOURNIER
Function: President