EU DECLARATION OF CONFORMITY

MANUFACTURER:

Company name: INNOV'SA
Unique registration number: FR-MF- 000006814
Head office address: 7 Avenue Bernard Pieds - 10110 BAR-SUR-SEINE

INNOV'SA:

- certifies that the EU Declaration of Conformity is issued under our sole responsibility as manufacturer
- hereby certifies that the devices listed below comply with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

PRODUCT:

Basic UDI: 3665533ESSENTIELEEU

Trade name: ESSENTIEL E

Model: ESSENTIEL E with electric tilt

Product references: ESS2_T04 / ESS2_T05 / ESS2_T06 / ESS2_T07 / ESS2_T08 / ESS2_T09 / ESS2_T10 / ESS2_T11 / ESS2_T12 / ESS2_T13 / ESS2_T14 / ESS2_T15 / ESS2_T16 / ESS2_T17 / ESS2_T18

Destination: Standard seat, shell seat

Risk class of the device according to Annex VIII: Class I

Harmonised standards used and against which conformity is declared:

- EN ISO 12183: 2014 Manually propelled wheelchairs - Requirements and test methods.
- EN ISO 14971: 2012 Medical devices - Application of risk management to medical devices.
- EN ISO 15223-1: 2016 Medical devices - Symbols for use with labels, labelling and information to be provided for medical devices - Part 1: General requirements.
- EN 60601-1:2006/A1: 2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- EN 60601-1-2: 2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
- Collateral Standard: Electromagnetic Interference - Requirements and Testing.

Place and date of issue:
Bar Sur Seine, 26 May 2021

Name and position of signatory:
Bruce Andurand, President

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