

## EU DECLARATION OF CONFORMITY

### MANUFACTURER:

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Company name: INNOV'SA  
Unique registration number: FR-MF- 000006814  
Address of the head office: 7 Avenue Bernard Pleds - 10110 BAR-SUR-SEINE

### INNOV'SA:

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- 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:

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Basic UDI-ID: 3665533ESSENTIALSW

Trade name: ESSENTIEL

Model: ESSENTIEL with manual tilt

Product references: ESS1\_T04 / ESS1\_T05 / ESS1\_T06 / ESS1\_T07 / ESS1\_T08 / ESS1\_T09 /  
ESS1\_T10 / ESS1\_T11 / ESS1\_T12 / ESS1\_T13 / ESS1\_T14 / ESS1\_T15 / ESS1\_T16 / ESS1\_T17 /  
ESS1\_T18

Destination: Standard seat, shell seat

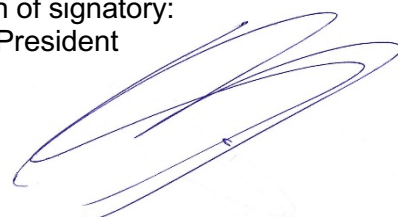
Risk class of the device according to Annex VIII: Class I

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



INNOV'SA

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