

Declaration of Conformity



This declaration of conformity is issued under the sole responsibility of the company and manufacturer:

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Object of the declaration:

Armon Elemento



Unique identification of the object:

SN: ELxxxxxx (product and serial number)

SRN:

NL-MF-000002064

Description of object:

Electronically controlled, mechanical arm support

The object of the declaration described above is in conformity with the relevant Community harmonization legislation:

MDR (EU2017/745)
EN ISO 22523:2006
EN 60601-1:2006

The object of the declaration described above meets the demands for CE labeling:

Medical Device Class I

Basic UDI-DI:


87202996137elementoGZ

The Basic UDI- DI also applies to all related Elemento products:

Description	UDI-DI
Elemento Light Right	08720634840378
Elemento Light Left	08720634840385
Elemento Right	08720634840392
Elemento Left	08720634840408
Elemento M1 Wireless Control	08720634840415
Elemento Controller	08720634840422
Elemento Power Cable	08720634840439
Elemento Compact Demo Stand	08720634840446
Elemento Compact Demo Stand Casters	08720634840453
Elemento Floor Stand w battery	08720634840460

Date and place

2021-10-04, Dongen, The Netherlands


R.P. Mastenbroek
Managing Director


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