

EC DECLARATION OF CONFORMITY

Manufacturer:

Indes Healthcare B.V.
Josink Esweg 1
7545 PN Enschede
The Netherlands

Products: Patient lifts

| Trade names / Models | Basic UDI-DI | UDI-DI |
|---------------------------|-------------------|----------------|
| esense Rise | 87202994521RISE5Q | 08720299452169 |
| Slingcare Go Up | 87202994521RISE5Q | 08720299452176 |
| esense Line | 87202994521LINE3X | 08720299452107 |
| esense Line+ | 87202994521LINE3X | 08720299452114 |
| esense Line200 | 87202994521LINE3X | 08720299452121 |
| esense Line230 | 87202994521LINE3X | 08720299452138 |
| SlingCare Straight | 87202994521LINE3X | 08720299452145 |
| SlingCare Straight Up | 87202994521LINE3X | 08720299452152 |
| SlingCare Straight Up 200 | 87202994521LINE3X | 08720299452190 |
| SlingCare Straight Max | 87202994521LINE3X | 08720299452183 |

Classification: Class I according to rule 13 of Regulation (EU) 2017/745

Indes Healthcare B.V. declares that the above mentioned products:

- meet the relevant provisions of following regulations/directives:
 - Medical Device Regulation (EU) 2017/745
 - RoHS 2011/65/EU
- comply to the applicable general safety and performance requirements as defined in Annex I of Regulation (EU) 2017/745.
- have technical documentation available in accordance with Annex II and Annex III of Regulation (EU) 2017/745.
- are designed, manufactured and tested in accordance with the quality management system of Indes Holding B.V. which complies to EN ISO 13485:2016 and art.10-9 of Regulation (EU) 2017/745.

This declaration of conformity is issued under the sole responsibility of Indes Healthcare B.V



Enschede, 02-04-2024
Niek Kottink
Managing Director

Indes Healthcare B.V.

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