EC DECLARATION OF CONFORMITY

Manufacturer:
Indes Production Management B.V.
Colosseum 20
7521 PT Enschede
The Netherlands
SRN: NL-MF-000000051

Products: Indes Patient lifts

Trade names / Models	Basic UDI-DI
esense Rise SlingCare Go Up	Basic UDI-DI: 87202994521RISE5Q
esense Line esense Line+ esense Line200 esense Line230 SlingCare Straight SlingCare Straight Up	Basic UDI-DI: 87202994521LINE3X

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

Indes Production Management B.V.declares that the above mentioned product(s):

- meet the relevant provisions of following regulations:
  - Medical Device Regulation (EU) 2017/745
- 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.
- meet the relevant provisions of following directives:
  - RoHS 2011/65/EU
  - Non-automatic weighing instruments (NAWI) Directive 2014/31/EU. (only applicable for esense Line200 and esense Line230 with Scale3 option)
    This is based on CE certificate with reference number T11978, initially issued in Sept 2021 by NMI Certin B.V. with Notified Body Identification Number 0122.
- comply to the applicable essential requirements as defined in Annex I of Directive 2014/31/EU (only applicable for esense Line200 and esense Line230 with Scale3 option)
- 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.

Applied standards:

Reference	Title
ISO 10535:2006	Hoists for the transfer of disabled persons - Requirements and test methods
EN 14971:2012	Medical devices - Risk management
EN 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 60601-1:2013	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 disturbances - Requirements and tests
Only applicable for esense Line200 and esense Line230 with Scale3 option:	
EN 45501:2015	Metrological aspects of non-automatic weighing instruments
OIML R 76 (2006)	Non-automatic weighing instruments – Part 1: Metrological and technical requirements - Tests

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

Niek Kottink, Managing Director

Enschede
The Netherlands
Date: 1 nov 2021