

EU DECLARATION OF CONFORMITY

We, the manufacturer, Novymed Export BV, SRN NL-MF-000044716, declare under our sole responsibility that the product(s) listed below are in conformity with the following EU directives and regulations:

- EU 2017/745 Medical Device Regulation including amendments
- 2011/65/EU RoHS II directive including supplements
- 2012/19/EU WEEE directive including amendments

Product name	Trade name	Product ref.	Basic UDI-DI	MDR risk class
DOC-series	DOC Neo	DOC Neo Operating Chair	872089254740DOCZ2	I (rule 13)

Intended use

The DOC-series chairs are electrically adjustable and mobile operating chairs intended for use during ophthalmology, ENT, oral and plastic surgery. The DOC-series chairs are intended for use by medical professionals.

Applied common specifications and standards

- EN 60601-1:2020 - General requirements for basic safety and essential performance
- EN-IEC 60601-1-2:2020 - Collateral standard: Electromagnetic compatibility
- EN-IEC60601-2-46:2019: Particular requirements for basic safety and essential performance of operating tables
- ISO 15223-1:2021 - Symbols for use in the labeling of medical devices
- EN ISO 14971:2021- Application of risk management to medical devices
- EN 62304:2015 - Medical device software - Software life-cycle processes
- EN 62366-1:2020 Medical devices - Application of usability engineering to medical devices

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Place and date of issue: Gorinchem, Octobre 24th, 2024

Signature:

