MANUFACTURER: ZARYS International Group sp. z o.o. sp.k.

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CLASSIFICATION	Class IIa medical device compliant with Directive 93/42/EEC (MDD) Personal Protective Equipment Category III according to PPE Regulation (EU) 2016/425

INTENDED PURPOSE

- device intended for use by medical staff in the operating theatre environment to provide a barrier to the transmission of micro-organisms between the operator and the patient, minimising the risk of cross-contamination

FEATURES

- **raw material**: 100% natural rubber latex
- **colour**: white and cream
- **cuff:** rolled
- **powder**: slightly powdered with maize flour for easy donning and doffing, and to minimise the risk of skin irritation, powder content ≤ 10mg/dm2
- **AQL**: 0,65
- **internal surface**: slightly powdered with maize flour
- **outer surface:** smooth with micro-texture over the entire grip area
- made from high quality natural latex, providing excellent flexibility, durability and fit to the hand
- the ergonomic shape of the gloves ensures comfort during long-term surgical procedures, and the micro-textured surface provides a secure grip for instruments
- used in general surgery and other specialised surgical procedures requiring sterile conditions
- provides protection against the penetration of hazardous chemicals, increasing the safety of medical staff when working with, for example, cytotoxic drugs
- packaging ensures easy access and optimal storage of gloves, helping to maintain a high standard of hygiene and safety standards, protecting against contamination
- the dispenser's ability to be opened both vertically and horizontally allows for easy adaptation to almost any space
- an additional opening for returning unopened pairs of gloves saves time and increases staff efficiency
- compact packaging reduces the space required for storage and means less cardboard is used, which contributes to reduced waste and a lower environmental impact
- **compliance with the standards:**
  EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, EN ISO 21420:2020, EN ISO 10993-1:2020, EN ISO 10993-4:2017, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-18:2020/A1:2023, EN ISO 10993-23:2021, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018+ EN ISO 11737-1:2018/A1:2021, EN ISO 11135:2014, EN ISO 11137-1:2015, EN ISO 11137-2:2015+A1:2023, EN ISO 11137-3:2017, EN ISO 14971:2019+EN ISO 14971:2019/A11:2021, EN ISO 15223-1:2022, EN ISO 20417:2021, EN 62366-1:2015+EN 62366-1:2015/A1:2020, ISO 10282:2023, ISO 2859-1:1999/Amd 1:2011, ASTM D5712, ASTM D5151,

ASTM D6124, ASTM D7160, ASTM D3577, ASTM D6978, ASTM F1671, EN ISO 21171:2006

- **quality assurance system**: manufacturing process in accordance with EN ISO 9001 and EN ISO 13485 and EN ISO 14001
- **intermediate packaging**: 50 pairs
- **size**: available in sizes 5.5 to 9.0
- **single-use**
- **sterile – radiation**
- **shelf life**: 5 years

CATALOGUE NUMBER	SIZE	INTERMEDIATE PACKAGING	TRANSPORT PACKAGING
RCHLP-55-50-03	5½	50 pairs	8 x 50 pairs
RCHLP-60-50-03	6	50 pairs	8 x 50 pairs
RCHLP-65-50-03	6½	50 pairs	8 x 50 pairs
RCHLP-70-50-03	7	50 pairs	8 x 50 pairs
RCHLP-75-50-03	7½	50 pairs	8 x 50 pairs
RCHLP-80-50-03	8	50 pairs	8 x 50 pairs
RCHLP-85-50-03	8½	50 pairs	8 x 50 pairs
RCHLP-90-50-03	9	50 pairs	8 x 50 pairs