| CE marking | Class I medical device in accordance with EU 2017/745 Personal protective equipment category III in accordance with Regulation (EU) 2016/425 CAT. III |
|---------------------------------------|---|
| CH REP | Swiss AR Services AG, Industriestrasse 47, 6300 Zug, Switzerland |
| EN ISO 21420:2020 | Standard: Protective gloves - General requirements and test methods www.wiros.de/IFU |
| EN 455-1:2022 | Medical gloves for single use - Part 1: Requirements and testing for freedom from holes AQL 1.5 |
| EN 455-2:2015 | Medical gloves for single use - Part 2: Requirements and testing for physical properties |
| EN 455-3:2015 | Medical gloves for single use - Part 3: Requirements and testing for biological evaluation LATEX i* |
| EN 455-4:2009 | Medical gloves for single use - Part 4: Requirements and testing for shelf life determination |
| EN ISO 374-1:2016 + A1:2018 TYPE C | Standard: Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. |
| EN ISO 374-2:2019 | Protective gloves against dangerous chemicals and microorganisms - Part 2: Determination of resistance to penetration |
| EN ISO 374-4:2019 | Protective gloves against dangerous chemicals and microorganisms - Part 4: Determination of resistance to degradation by |
| EN ISO 374-5:2016 VIRUS | Standard: Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organism risks |
| | The penetration resistance is assessed under laboratory conditions and refers solely to the tested samples. |
| VO (EU) 2023/988 | Regulation (EU) Nr. 2023/988 on general product safety. |
| VO (EG) 1935/2004 | Regulation regarding plastic materials and articles intended to come into contact with food. |
| VO (EU) 10/2011 | Regulation on plastic materials and articles intended to come into contact with food |
| | |