





CE marking	Class I medical device in accordance with EU 2017/745 Personal protective equipment category III in accordance with Regulation (EU) 2016/425	<div>CE 2777</div> <div>MD CLASS I</div> <div>PPE CAT. III</div>				
CH REP	Swiss AR Services AG, Industriestrasse 47, 6300 Zug, Switzerland					
EN ISO 21420:2020	Standard: Protective gloves - General requirements and test methods	<div> www.wiros.de/IFU</div>				
EN 455-1:2022	Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	<div>AQL 1.5</div>				
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					
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. <table><tr><th>Test chemical</th><th>Level</th></tr><tr><td>K Sodium Hydroxide 40%</td><td>6</td></tr></table>	Test chemical	Level	K Sodium Hydroxide 40%	6	<div> K</div>
Test chemical	Level					
K Sodium Hydroxide 40%	6					
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	<div> VIRUS</div>				
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.	<div></div>				
VO (EU) 10/2011	Regulation on plastic materials and articles intended to come into contact with food					
XXI/1.	Recommendation of the Federal Institute for Risk Assessment XXI/1. on commodities based on natural and synthetic rubber in contact with food					