





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 B	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><tr><td>P Hydrogen Peroxide 30 %</td><td>3</td></tr><tr><td>T Formaldehyde 37%</td><td>6</td></tr></table>	Test chemical	Level	K Sodium Hydroxide 40%	6	P Hydrogen Peroxide 30 %	3	T Formaldehyde 37%	6	<div> KPT</div>
Test chemical	Level									
K Sodium Hydroxide 40%	6									
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T Formaldehyde 37%	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 <table><tr><th>Test</th><th>Result</th></tr><tr><td>Protection against bacteria and fungi</td><td>Passed</td></tr><tr><td>Protection against bacteria, fungi and viruses</td><td>Passed</td></tr></table>	Test	Result	Protection against bacteria and fungi	Passed	Protection against bacteria, fungi and viruses	Passed	<div> VIRUS</div>		
Test	Result									
Protection against bacteria and fungi	Passed									
Protection against bacteria, fungi and viruses	Passed									
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									