

List of Harmonized Standard Surgical Gloves			Prepared by	Zhang Bi Yong
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Doc. No.	AR/CE01-03		Zhang Bi Wen	Zhang Bi Wen
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List of harmonized standard

List of European Union Harmonized Standards which this product applies.

Standard/Directive	Name of document
93/42/EEC	Medical device directive
EN 455-1:2000	Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
EN 455-2:2009+A2:2013	Medical gloves for single use - Part 2: Requirements and testing for physical properties
EN 455-3:2006	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 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009+AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 11137-1: 205	Sterilization of health care products Radiation-Part 1 : Requirements for development, validation and routine control of a sterilization process for medical devices.
EN ISO 11137-2: 2015	Sterilization of health care products Radiation -Part 2 Establishing the sterilization dose
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices- Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices- Part 2: Validation requirements for forming, sealing and assembly process
EN ISO 11737-1:2006	Sterilization of medical devices- Microbiological methods-Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices- Microbiological methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices.
EN ISO 15223-1:2016	Symbols for use in the labeling of medical devices

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EN 62366:2008	Medical devices - Application of usability engineering to medical devices
ISO 10282:2014	Single-use sterile rubber surgical gloves - Specification
ISO 10993-10:2010	Biological Evaluation of Medical Device-Part 10:stimulation and allergic reaction
EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms — Part 5: Terminology and performance requirements for micro-organisms risks
EN ISO 374-1:2016	Protective gloves against dangerous chemicals and micro-organisms — Part 1: Terminology and performance requirements for chemical risks
EN ISO 374-4:2019	Protective gloves against dangerous chemicals and micro-organisms — Part 4: Determination of resistance to degradation by chemicals
EN ISO 374-2:2019	Protective gloves against dangerous chemicals and micro-organisms — Part 2: Determination of resistance to penetration



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