ICEMEDICS®

QUALITY

Regulation and applicable standards

- Personal Protective Equipment (PPE) Regulation (EU) 2016/425
- Medical Devices Regulation (EU) 2017/745
- Food Contact Regulation (EU) 10/2011
- CE Certification

QUALITY, our commitment.

ICEMEDICS®

At ICEMEDICS, quality is our absolute priority. Our mission is to provide our clients with personalized advice and develop high-quality products, whether in terms of design, manufacturing, or compliance with the most demanding standards.

Our commitment to the quality of gloves goes far beyond standards and certifications. We monitor every step of their production, controlling their composition to minimize any potential skin irritation, ensure optimal adaptability, and maximize sensitivity.

The glove industry is rigorously regulated, with strict standards based on their use. All our gloves come with the European Declaration of Conformity, in accordance with Regulation (EU) 2016/425, ensuring their compliance with European standards.

ICEMEDICS is registered as the person responsible for placing sanitary products on the market (RPS) with the Spanish Agency of Medicines and Medical Devices (AEMPS), under the code:

RPS/778/2023

As an authorized legal representative in Europe, **ICEMEDICS** provides the greatest assurance to our clients. Our SRN registration number is:

SRN: ES-AR-000035147
https://ec.europa.eu/tools/eudamed/#/screen/search-eo

ICEMEDICS also holds a license to import sanitary products issued by the Spanish Agency of Medicines and Medical Devices, under registration number:

6911- PS

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Regulation on Personal Protective Equipment (PPE) (EU) 2016/425

CE Marking of Protective Gloves

Protective gloves, as Personal Protective Equipment (PPE), play a crucial role in ensuring the safety of workers. Before the introduction of Regulation (EU) 2016/425, these products were certified in accordance with the European Directive 89/686/EEC. This directive served as the previous regulatory framework, establishing safety standards and certification procedures for PPE.

With the implementation of the new regulation, protective gloves are now subject to updated standards and more rigorous certification procedures. The visible indication of compliance, symbolized by the CE marking, remains crucial. This marking serves as assurance, not only for competent authorities but also for users, confirming that the PPE meets all mandatory legislative requirements.

This certification and CE marking process ensures compliance not only with minimum safety standards but also with the new requirements introduced by the 2016 regulation. Users can thus have increased confidence in the quality and performance of protective gloves, reinforcing the protection of workers in various professional environments.

Regulation on Personal Protective Equipment (PPE) (EU) 2016/425

New PPE Regulation (EU) 2016/425

Since April 21, 2018, Directive 89/686/EEC has been replaced by the new Regulation (EU) 2016/425 of the European Parliament and Council, dated March 9, 2016, concerning Personal Protective Equipment (PPE). This new regulation goes far beyond a mere update, aiming to significantly improve worker safety and the quality of PPE placed on the market.

One of the major advancements of this regulation lies in the harmonization of standards across the European Union. This means that PPE must now meet strict requirements, ensuring increased compliance with safety standards. The benefits of this harmonization include enhanced worker protection, facilitation of cross-border trade, and a reduction of barriers to the exchange of goods within the European Single Market.

Starting April 21, 2018, Regulation (EU) 2016/425 enabled the placing on the market of Personal Protective Equipment (PPE) bearing the CE mark. From April 21, 2019, it became mandatory for all PPE products placed on the market to be certified in accordance with this regulation and bear the CE marking. As of April 2023, no product not meeting these regulatory requirements can be marketed.

The transition from the PPE Directive to the PPE Regulation brought about several significant changes. Among the key ones:

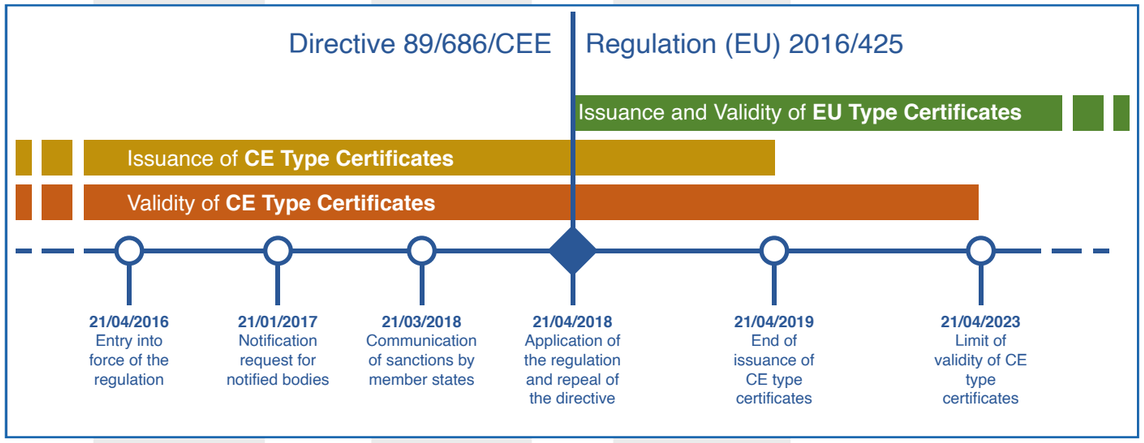
- Modification of product categorization related to associated risks: This modification aims to better classify PPE based on their field of application, ensuring a more precise match with user needs.
- Change in the classification of certain product categories: Some product categories have been reevaluated to more accurately reflect their level of risk.
- Systematic CE Declaration of Conformity: A CE Declaration of Conformity, accompanied by detailed product information, must be provided with each PPE. It can also be accessible via a web link.
- 5-year validity/expiry date for new EU certificates: CE certificates of conformity now have a validity period of 5 years, requiring regular product monitoring and updates.

The regulation has strengthened the obligations of «economic operators,» including manufacturers, importers, and distributors. They are now required to have a better understanding of the products they market and take responsibility for their sale.

Regulation on Personal Protective Equipment (PPE) (EU) 2016/425

New PPE Regulation (EU) 2016/425

In summary, the new PPE Regulation (EU) 2016/425 represents a major advancement for workplace safety in Europe. It ensures higher standards, improved worker protection, and simplifies cross-border trade. This regulation underscores the European Union's commitment to workplace safety and the quality of PPE placed on the market.



Regulation on Personal Protective Equipment (PPE) (EU) 2016/425

Category Classification

Category of PPE	Description of Category	Activity
Category I	Simple PPE, products are designed to provide protection against minor risks.	The manufacturer is responsible for the compliance of its products with the essential requirements of the Directive.
Category II	Intermediate PPE intended to provide protection against intermediate risks.	The products have obtained a certificate of conformity from a notified body. This ensures an additional level of control and verification of compliance.
Category III	Complex PPE designed to offer maximum protection against serious risks.	The products not only require an initial certificate of conformity but also regular production control by the manufacturer through notified bodies. Continuous production control ensures consistent quality over time.

All our Personal Protective Equipment (PPE) falls under Category III.

Regulation on Personal Protective Equipment (PPE) (EU) 2016/425

PPE legislation
EN ISO 21-420 Standards

The EN ISO 21-420 standards play a crucial role in the protective glove industry, ensuring quality, safety, and compliance. This standard establishes general requirements and appropriate testing procedures for the manufacturing and design of each protective glove. Each protective glove is marked with a series of crucial information:

- It includes the name, brand, or any other means of identification of the manufacturer or its authorized representative.
- The glove's designation and size are also clearly indicated to assist users in choosing the appropriate product.
- If necessary, marking related to the expiration date is included to ensure that the gloves remain effective throughout their lifespan.

UNE-EN 420. GENERAL REQUIREMENTS			
Hand Sizes	Glove Dimensions		
Sizes	Circumference in mm	Length in mm	Minimum Glove Length
6	152	160	220
7	178	171	230
8	203	182	240
9	229	192	250
10	254	204	260
11	279	215	270

When the glove complies with one or more European standards, it also bears the appropriate pictogram for that standard. This mark is a tangible sign of compliance with established safety standards, reassuring users about the quality and reliability of the product.

In summary, the EN ISO 21-420 standards are the cornerstone of quality and safety in the protective glove industry. They ensure that each glove meets stringent requirements, thereby contributing to the protection and safety of workers. Compliance with these standards is a mark of confidence for users and underscores the industry's commitment to high standards.

Regulation on Personal Protective Equipment (PPE) (EU) 2016/425

PPE legislation
EN 374 1-5 standards

EN 374-1:2016 (PPE Legislation - Chemical Risks)

Protective gloves against chemical products are subject to strict regulations, as defined in the EN 374-1:2016 standard. This standard plays a crucial role in the Personal Protective Equipment (PPE) industry, ensuring the quality and safety of gloves designed to resist potentially hazardous chemicals.

The EN 374-1:2016 standard is based on three crucial test methods to assess the performance of gloves: penetration, permeation, and degradation. These tests are designed to ensure that gloves provide reliable protection against aggressive chemicals.

Gloves are classified into three distinct types: Type A, Type B, and Type C. Each type is associated with specific requirements that determine their ability to resist chemical penetration. Here is an overview of the classifications and requirements:

A SINGLE PICTOGRAM FOR 3 TYPES OF GLOVES		
Glove Types	**Requirement**	**Logo**
Type A	Penetration Resistance (EN 374-2) Passage Time ≥ 30 min for at least 6 products from the new list (EN 16523-1)	EN ISO 374-1 / Type A AJKLPR
Type B	Penetration Resistance (EN 374-2) Passage Time ≥ 30 min for at least 3 products from the new list (EN 16523-1)	EN ISO 374-1 / Type B JKL
Type C	Penetration Resistance (EN 374-2) Passage Time ≥ 10 min for at least 1 products from the new list (EN 16523-1)	EN ISO 374-1 / Type C

According to this regulation, all our gloves belong to Category B

It is important to note that the new list (EN 16523-1) includes specific chemicals for which gloves must be tested. Compliance with these requirements is essential to ensure that gloves provide adequate protection.

Regulation on Personal Protective Equipment (PPE) (EU) 2016/425

PPE legislation EN 374 1-5 standards

According to this regulation, all our gloves belong to Category B, meaning they offer high resistance to penetration for a wide range of chemicals. When choosing protective gloves, be sure to consider these classifications to ensure you get the necessary protection against the chemical risks you may encounter.

Adhering to these standards is essential to ensure the safety and health of workers in environments where chemicals are present.

EN 374-5:2016 (PPE Legislation - Chemical Risks)

Protective gloves against chemical and hazardous microorganisms, including bacteria, fungi, and viruses, are subject to rigorous standards to ensure their effectiveness.

The EN 374-5:2016 regulation expands glove protection beyond chemical risks, now including protection against viruses. Gloves must pass the penetration resistance test according to the EN 374-2:2014 standard to ensure their overall quality and performance.

It should be noted that the possibility of assigning protection against viruses has been added, provided that the glove undergoes the ISO 16604:2004 test (method B). This means that gloves bearing the «EN 375-5:2016 VIRUS» pictogram have been tested for their ability to protect against viruses, in addition to bacteria and fungi.

The following table explains the two pictograms:

- **Bacteria and Fungi Protection:** gloves offering protection against bacteria and fungi, crucial in many work environments.

- **Bacteria, Fungi, and Virus Protection:** gloves providing complete protection against bacteria, fungi, and viruses. This category is particularly relevant in the current context, where protection against viruses has become crucial.

Regulation on Personal Protective Equipment (PPE) (EU) 2016/425

PPE legislation EN 374 1-5 standards

Another important aspect of the EN 374-5:2016 regulation is the classification of gloves based on their permeability resistance. This classification is based on the average penetration time, with performance levels ranging from Class 1 to Class 6.

Penetration	Permeation
10	Classe 1
30	Classe 1
60	Classe 1
120	Classe 1
240	Classe 1
480	Classe 1

Protective gloves are also tested for their resistance against a specific list of chemicals. This list includes various chemicals, each associated with a letter code, a designation of the chemical, a CAS number, and a class.

Code	Chemical	CAS No.	Class
A	Methanol	67-56-1	Primary Alcohol
B	Acetone	67-64-1	Ketone
C	Acetonitrile	75-05-8	Organic compound containing nitrile groups
D	Didromethane	75-09-2	Chlorinated hydrocarbon
E	Carbon disulfide	75-15-0	Organic compound containing sulfur
F	Toluene	108-88-3	Aromatic hydrocarbon
G	Diethylamine	109-89-7	Amine
H	Tetrahydrofuran	109-99-9	Heterocyclic compound and ether
I	Ethyl acetate	141-78-6	Ester
J	N-heptane	142-85-5	Saturated hydrocarbon
K	Sodium hydroxide 40%	1310-732	Inorganic base
L	Sulfuric acid 96%	7664-93-9	Inorganic mineral acid
M	Nitric acid 65%	7697-37-2	Inorganic mineral acid, oxidizing
N	Acetic acid 99%	64-19-7	Organic acid
O	Ammonium hydroxide 25%	1332-21-6	Biological base
P	Hydrogen peroxide 30%	7722-84-1	Peroxide
S	Hydrofluoric acid 40%	7664-39-3	Inorganic mineral acid
T	Formaldehyde 37%	50-00-0	Aldehyde

Using gloves compliant with the EN 374-5:2016 regulation is essential to ensure the safety and health of workers exposed to chemical and microbiological risks. These gloves offer reliable and versatile protection, covering a broad range of potential risks. It is crucial to choose the appropriate gloves based on the specific risks you may face, including considering protection against viruses in the current context.

Regulation on Personal Protective Equipment (PPE) (EU) 2016/425

These certificates comply with EU 2016/425 Regulations

VINYL CERTIFICATE 2777/15556-01/E00-00

Issued to:
Guangzhou GioTech Co., Ltd
Room 1-219, No.85 LuoJiaCun ShiLian Road
DaLong Street
Panyu District
Guangzhou
Guangdong
511430
China

Notified Body: 2777

SATRA customer number: P20285

EU Type-Examination Certificate

Certificate number: 2777/15556-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:	**Description:**
GV-001	Disposable Vinyl Powder-Free Gloves. Colours: Clear, Blue, Pink.

Sizes:
S(6)
M(7)
L(8)
XL(9)

Classification:

EN ISO 374-1:2016+A1:2018 /Type B	**Level**	**EN ISO 374-4:2019 Degradation %**
40% Sodium Hydroxide (K)	6	-27.4
30% Hydrogen Peroxide (P)	5	-10.8
37% Formaldehyde (T)	5	-19.7

EN ISO 374-5:2016	
Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0300385/2029, CHT0304908/2046, CHM0300557/2030/LC/A, CHM0300557/2030/LC/B, CHM0301829/2035/LC

Signed on behalf of SATRA: Daisy He Daisy He Quincey Brown

Date first issued: 04/01/2021
Date of issue: 04/01/2021
Expiry date: 04/01/2026

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SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland.

Regulation on Personal Protective Equipment (PPE) (EU) 2016/425

These certificates comply with EU 2016/425 Regulations

NITRILE CERTIFICATE 2777/20730-02/E00-00

Issued to:
Guangzhou GioTech Co., Ltd
RM 209, Building 4, No.85 LuoJia Village
ShiLian Road, Dalong Street
Panyu District
Guangzhou City
Guangdong Province
China

Notified Body: 2777

SATRA customer number: P20285

EU Type-Examination Certificate

Certificate number: 2777/20730-02/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product reference:	**Description:**
GN-001	Disposable Nitrile Powder-Free Glove Available colours in Black, Blue, Green, Violet, White

Sizes:
6/S, 7/M, 8/L, 9/XL

Classification:

EN ISO 374-1:2016+A1:2018 /Type B	**Level**	**EN ISO 374-4:2019 Degradation %**
40% Sodium Hydroxide (K)	5	-3.8
30% Hydrogen Peroxide (P)	2	4.5
37% Formaldehyde (T)	5	12.8

EN ISO 374-5:2016	
Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0312828/2118, CHM0313506/2120/LC/A, CHM0313506/2120/LC/B

Signed on behalf of SATRA: Kayleigh Aylward Kayleigh Aylward

Date first issued: 23/03/2022
Date of issue: 12/09/2023
Expiry date: 12/09/2028

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Regulation on Medical Devices (EU) 2017/745

Regulation on Medical Devices

This regulation applies to medical products and their accessories.

This regulation is a critical directive for medical products and their accessories, establishing stringent standards to ensure the safety and effectiveness of these products. Under Regulation (EU) 2017/745, a medical product is defined as any instrument, device, equipment, material, or other article, used alone or in combination, including computer programs, intended by the manufacturer to be used on humans.

The regulation categorizes medical products into four classes, reflecting the level of risk associated with each class:

- Class I: Encompasses products with the lowest risk, often including non-invasive and short-term items.
- Class IIa and IIb: Includes products with moderate risk, such as some invasive and long-term medical devices.
- Class III: Corresponds to products with the highest risk, often involving implantable and highly invasive medical devices.

Each class is subject to specific compliance and documentation requirements, and manufacturers must follow rigorous procedures to ensure the quality and safety of their products.

Additional Points to Include:

1. Definition of Classes: Each class is determined by specific criteria, including duration of use, degree of invasiveness, and potential risk. It is crucial for manufacturers to understand these criteria to correctly classify their products.
2. Compliance Requirements: Manufacturers must comply with various requirements, such as conducting risk assessments, implementing quality control procedures, and conducting appropriate clinical trials.
3. Certification Process: The certification process involves several stages, from initial design to market placement, with ongoing assessments to ensure compliance throughout the product's lifecycle.
4. Manufacturer Responsibilities: Manufacturers are responsible for designing safe and effective products, documenting manufacturing processes, and monitoring product safety after market placement.
5. Regulatory Updates: Manufacturers must stay informed about potential regulatory updates and adjust their processes accordingly to ensure ongoing compliance.En résumé, le règlement sur les produits sanitaires (UE) 2017/745 établit des normes strictes pour garantir la qualité et la sécurité des produits sanitaires, nécessitant une compréhension approfondie et une conformité continue de la part des fabricants.

In summary, Regulation (EU) 2017/745 on medical products establishes strict standards to ensure the quality and safety of medical products, requiring in-depth understanding and ongoing compliance from manufacturers.

Regulation on Medical Devices (EU) 2017/745

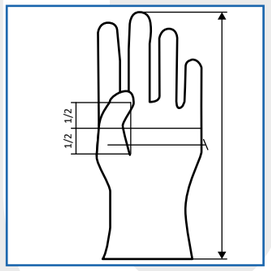
Standards EN 455 1-2-3-4

This regulation applies to medical products and their accessories.

The European standard **EN 455 1-2-3-4** defines requirements and test methods to evaluate the physical properties of single-use medical gloves. The goal is to ensure that they provide and maintain an adequate level of protection against cross-contamination, ensuring the safety of both the patient and the user during their use.

Requirements and tests:

- **EN 455-1:2001 Hole Test - AQL Verification (<=1.5)**
  This part of the standard aims to ensure the absence of holes in medical gloves, verified by an analysis of the Acceptable Quality Level (AQL) equal to or less than 1.5. Air and water tests are used to determine the degree of porosity of the glove.
- **EN 455-2:2015 Physical Properties**
  The requirements defined by the UNE-EN 455-2:2015 for examination gloves include specific dimensions, ensuring suitability for different sizes, from very small to very large.



Size	Median length (mm)	Median width (mm)
Extra small	≥ 240	≤ 80
Small		80 ± 10
Medium		95 ± 10
Large		110 ± 10
Extra Large		≤ 110

Force au point de rupture		
Tested in accordance with section 5.2 and tested within 12 months of manufacture in accordance with section 5.3	Surgical gloves	Exam/Procedure Gloves
	≥ 9.0 N [a]	≥ 6.0 N [b] ≥3.6 N [c]

(a) Requirements for surgical gloves.
(b) Requirements for all examination gloves, except gloves made of thermoplastic materials (e.g., polyvinyl chloride, polyethylene).
(c) Requirements for all gloves made from thermoplastic materials (e.g., polyvinyl chloride, polyethylene).

Regulation on Medical Devices (EU) 2017/745

Standards EN 455 1-2-3-4

This regulation applies to medical products and their accessories.

- **EN 455-3:2015 Biological Evaluation**
  Biological evaluation tests are crucial to determine the suitability of materials used in glove manufacturing. This includes analyses of extractable latex proteins, bacterial endotoxins, and powder content.

- **EN 455-4:2010 Determination of Shelf Life**
  The standard specifies procedures for testing the shelf life of medical gloves, allowing the assignment of an effective expiration date. This ensures users that the glove will maintain its quality throughout its lifespan.

Context and importance
The EN 455-1-2-3-4 standard fits into a broader framework of ensuring the safety of single-use medical products, emphasizing the importance of consistent production and high-quality standards.

Evolution and Harmonization: The constant evolution of these standards demonstrates a commitment to continuous improvement, encouraging harmonization with international standards for global compliance.

Training and Awareness
User awareness of these standards, including information on the specific properties tested, is crucial to ensure proper use and ongoing confidence in the products.

Future Perspective
Anticipating future developments, this chapter provides a forward-looking vision, highlighting potential changes and new requirements that could influence the manufacturing and use of medical gloves.

Case Studies
Real case studies illustrating the positive impact of compliance with these standards on product quality and patient safety can be integrated, reinforcing a practical understanding of their importance.

Regulation on Food Contact (EU) 10/2011

Food Contact

- **Regulation CE 1935/2004 :** This regulation is concerned with materials and objects intended to be in contact with foodstuffs, establishing standards to ensure the sanitary safety of materials used throughout the food production process.

- **Regulation CE 10/2011 :** This specific regulation focuses on materials and objects made of plastic that are intended to come into contact with foodstuffs. It sets comprehensive criteria and requirements to ensure the safety of plastics utilized in the context of food.

These regulations operate within a broader regulatory framework, which includes Regulation CE REACH and Regulation 2023/2006 on good manufacturing practices, among others. The overarching goal is to guarantee the safety and quality of materials employed in food contact, safeguarding the integrity of the food chain.

To enforce compliance, rigorous laboratory tests are conducted based on the intended use of materials. Simulators are employed to replicate real-world exposure conditions, considering factors such as the type of food in contact with the material, temperature, and contact durations. These thorough tests are instrumental in verifying that materials meet the required sanitary standards and pose no risk of contaminating food items. The holistic approach of these regulations reflects a commitment to upholding the highest standards of food safety and consumer protection.

CE Marking

Unique Device Identification (UDI)

CE Marking is a crucial indication of a product's compliance with European standards for health, safety, and the environment. It also encompasses a vital element known as the Unique Device Identification (UDI). The UDI is a unique numerical or alphanumeric code associated with a medical product, facilitating clear and indisputable identification in the market, thereby enhancing traceability.

The UDI consists of two distinct parts: a Product Identifier (UDI-DI) specific to the manufacturer and product, providing access to specific information, and a Production Identifier (UDI-PI) identifying the production unit of the product, if applicable, as well as packaged products.

According to the provisions of Article 27 of Regulation 2017/745 and Article 24 of Regulation 746/2017, the UDI system includes the creation of a UDI code, adding this code to the product label or packaging, storage by economic operators, healthcare facilities, and healthcare professionals, as well as the establishment of a dedicated electronic database for unique product identification («UDI database»).

Disposable gloves can be classified into several categories, including Category I, Medical Category I, Category III - PPE, and a mixed category combining Medical Category I and III. These categories provide access to crucial product information. The specificity of the UDI:

CE 2777 Personal Protective Equipment Category III
in accordance with European Regulation (EU) 425/2016
Notified Body 2777 SATRA Technology Europe Ltd Bracetown Business Park,
Clonee, Co. Meath D15 YN2P Ireland Tel: +353 1 437 2484

CE 2777 Medical Device Class I in accordance with European Regulation (EU) 745/2017 and
Personal Protective Equipment Category III in accordance with European Regulation (EU) 425/2016
Notified Body 2777 SATRA Technology Europe Ltd Bracetown Business Park,
Clonee, Co. Meath D15 YN2P Ireland Tel: +353 1 437 2484

- Enhances product traceability efficiency.
- Facilitates product retrieval.
- Prevents counterfeiting (MDR Article 123(3)(f), Article 27(4)).
- Improves patient safety.

The UDI-DI is the central element of the database and relevant documentation (certificates, declarations of conformity, technical documentation, and summaries on safety and clinical performance). It will also be the key to accessing product-related information entered into the future European Database on Medical Devices.

The new UDI system will streamline the traceability of medical products and strengthen post-market surveillance activities related to product safety, enabling better monitoring by competent authorities.

The obligation to use the UDI system takes effect from May 26, 2025 (MDR Article 123(3)(f), Article 27(4)).

CE Marking

Product quality Certification

MD Medical Device

Medical Device

21 PAP

PAP 21: Refers to any product or packaging made using non-corrugated cardboard.

30°C 10°C

Temperature Limits: Temperature range within which the shipping packaging must be handled.

Rain Protection: The transport packaging must be protected from rain.

To indicate that transport package shall not be exposed to sunlight.

Compliant with EU Food Handling Regulations: Adheres to European regulations for food handling.

Do not reuse

AQL 1.5

Quality Assurance: Acceptable level of quality.

EN ISO 374-1:2016+ A1:2018/Type B KPT

Chemical Protection: Provides protection against chemicals.

EN ISO 374-5:2016 VIRUS

Protection Against Chemicals and Hazardous Microorganisms: Protects against chemicals and hazardous microorganisms (bacteria, fungi, and viruses).

ASTM D 6319

ASTM D6319 is a standard specification for Nitrile Examination Gloves for Medical Application.

EN ISO 21420

Compliant with ISO 21420:2020:
Adheres to the ISO 21420:2020 standard.

NON STERILE

Non-Sterile: Indicates that the device, usually supplied sterile in identical or similar packaging, has not been sterilized.

ICEMEDICS®

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