Cabinet Resolution No. (83) of 2020
Regarding the UAE System for Personal Health Protection Products

The Cabinet:

- Having reviewed the Constitution;
- Federal Law No. (1) of 1972 Concerning the Jurisdictions of Ministries and the Powers of Ministers, as amended;
- Federal Law No. (37) of 1992 Concerning Trademarks, as amended;
- Federal Law No. (24) of 2006 Concerning Consumer Protection, as amended;
- Federal Law No. (14) of 2016 Concerning Administrative Violations and Sanctions in the Federal Government;
- Federal Law No. (19) of 2016 Concerning Combating Commercial Fraud;
- Federal Law No. (10) of 2018 Concerning Product Safety, as amended;
- Federal Decree by Law No. (20) of 2020 Concerning Specifications and Standards;
- Cabinet Resolution No. (22) of 2004 Concerning the Executive Regulation of the National Accreditation System;
- Cabinet Resolution No. (35) of 2015 Concerning the UAE Law for the Control of Conformity Assessment Bodies;
- Cabinet Resolution No. (3) of 2016 Concerning the UAE System for the Control of Equipment, Tools and Materials of the Personal Protection, Safety and Occupational Health; and
- Based on the proposal submitted by the Minister of Industry and Advanced Technology, and the approval of the Cabinet,

Has resolved:

Article (1)

Definitions

In application of the provisions of this Resolution, the following words and expressions shall have the meanings assigned thereto, unless the context otherwise requires:

State	:	United Arab Emirates.
Ministry	:	Ministry of Industry and Advanced Technology.
Competent Body	:	The Federal or Local Body concerned with the application of the provisions of this Resolution.
Standard Specification	:	A document that specifies the characteristics of the commodity, material, product, service, or whatever subject to measurement, as well as its description, characteristics, quality level, dimensions, standards, or safety and security requirements therein. Standard Specification also includes the terms, symbols, test methods, sampling, packaging, labels and marks.
Approved Standard Specifications	:	The standard specifications approved by the Ministry, which are referred to as UAE Standard Specification, and symbolized by (UAE.S).
Emirates Conformity Assessment Scheme (ECAS)	:	A Scheme issued by the Ministry, which is concerned with verifying whether the Product meets the requirements specified in the approved Standard Specifications, directly or indirectly, through specific procedures conducted by the Ministry, such as examination, testing, calibration, inspection or granting Conformity Certificates.
Conformity Certificate	:	A Certificate issued by the Ministry, which confirms the conformity of the Product or any batch thereof to the requirements of the Approved Standard Specifications.
Conformity Assessment	:	A Body registered, approved or accepted by the Ministry to carry out the Conformity Assessment Procedures in accordance with the relevant

Body		Legislation; including testing and calibration laboratories, inspection bodies, merit-testing bodies and certification bodies for systems, individuals or products.
Supplier	:	The manufacturer, packer, processor, importer, or stockiest of the Product, any major distributor, sub-distributor, or any person whose activities affect the Product characteristics, or any commercial or legal representative who is responsible for importing the Product.
Consumer	:	Any person who obtains a commodity or service with or without payment, satisfying his personal needs or the others needs.
Product	:	Any Personal Health Protection Products specified in the Annex attached to this Resolution.
Personal Health Protection Products	:	Any non-food or non-medicinal Product for protection, prevention and control of infection whose requirements and characteristics are specified in the Annex attached to this Resolution.
Supply Chain	:	All the stages that the Product goes through, starting from the primary production until its arrival to the Consumer, including its import, export, manufacture, preparation, processing, packaging, installation, transport, storage, distribution, introduction, offering, wholesale or retail sale and any other relevant process.
Launch	:	Any activity or procedure that aim at selling, offering, trading, marketing, promoting or introducing the Product to the Consumer, with or without a payment.

Article (2)

Scope of Application

The provisions of this Resolution shall apply to the Products whose Standard Specifications are indicated in the Annex attached to this Resolution, whether they are launched in the UAE markets, including free zones or for export outside UAE.

Article (3)

Supplier Liabilities

The Supplier, at any stage of the supply chain, shall comply with the following:

1. Carrying out his activity through a company or an individual establishment registered and licensed in accordance with the relevant Legislation;
2. Obtaining a Conformity Certificate for the Product before its launch in the market, in accordance with ECAS;
3. Ensuring that the product meets the technical requirements contained in the Approved Standard Specifications, indicated in the Annex attached to this Resolution;
4. Cooperating with the Ministry employees and the Competent Bodies and providing the required documents, including technical documents, certificates, data, information and test reports, upon request;
5. Ensuring that the Product meets this Resolution requirements;
6. Complying with the claim verification procedures stipulated in this Resolution; and
7. Any other obligations specified by the Ministry in coordination with the Competent Body.

Article (4)

Technical Requirements

The Product prepared for the purpose of launch or trade in the UAE market or for export shall meet the following requirements:

1. The Labels shall meet the requirements of the Standard Specification specified in the Annex attached to this Resolution;
2. The pictures and expressions used on the Product package shall not violate the public order, public morals and Islamic values prevailing in UAE; and
3. All information, pictures and indications used in the labels shall be correct and scientifically

and clinically proven.

Article (5)

Conformity Verification

1. The Supplier in UAE shall not launch the Product in the local markets or carry out promotional campaigns for the Product unless the Product is registered in accordance with ECAS.
2. The Ministry or the Competent Body, as the case may be, before granting the Product a Conformity Certificate, shall verify its conformity with the Approved Standard Specifications specified in this Resolution, including the verification of the following:
   a. The Supplier shall meet all procedures required to obtain the Conformity Certificate according to ECAS before launching the Product inside UAE or exporting it;
   b. The Product shall meet all the requirements of this Resolution and shall conform to the Approved Standard Specifications indicated in the Annex attached to this Resolution; and
   c. All technical documents, certificates, data and information shall confirm that the Product conforms to this Resolution requirements.

Article (6)

Requirements of the Conformity Assessment Body

The Conformity Assessment Body that assesses the Product Conformity shall meet the conditions and requirements specified by the Cabinet Resolution Concerning the UAE Law for the Control of Conformity Assessment Bodies.

Article (7)

Liabilities of the Competent Body

The Ministry or the Competent Body, as the case may be, shall implement the provisions of this Resolution, and for this purpose it may assume the following:

1. Verifying that the Product meets the requirements of conformity to the Standard Specifications indicated in the Annex attached to this Resolution, and that the technical documents required to be attached to the batch subject to examination are completed;
2. Taking all administrative procedures necessary to pull back or recall the Product that do not comply with this Resolution requirements;

3. Imposing the penalties referred to in Article (10) of this Resolution in the event of committing any of the violations referred to therein; and
4. Notifying the Ministry in the event that the Competent Body implements what is stated in Clauses (2) and (3) of this Resolution.

Article (8)

Market Survey and Control

1. When the Product is launched in the market, it shall be subject to the control. Therefore, the Ministry or the Competent Body, as the case may be, shall take the necessary measures to control the Product to ensure that it conforms to the Conformity Certificate in all stages of the supply chain. For such purpose, the Ministry or the Competent Body may take any of the following measures:
   a. Ensuring that all Product launch outlets in UAE are complied with prohibiting importing or launching it in the local markets, except after obtaining the Conformity Certificate;
   b. Pulling back samples of the Product, from the market or from the Suppliers warehouses, in order to conduct the necessary tests and ensure their compliance with this Resolution requirement;
   c. Taking the appropriate measures against the Products that violate the provisions of this Resolution, including suspending or cancelling the Conformity Certificate for the violating Products and pulling back and recalling non-conforming Products from the market; and
   d. Obliging the Supplier who is responsible for launching the violating Product, to recall and pull back it from the local market, and to regularize the product if this is possible or obliging the Supplier to return the Product to the country of origin or exporter or to destroy the product in accordance with the Legislation in force in this regard, within the period specified by the Ministry or the Competent Body, as the case may be.
2. The Supplier from whom the Product sample is taken shall be deemed responsible for the Product non-conformity to this Resolution requirements, unless proven otherwise, during the period specified by the Ministry or the Competent Body, as the case may be.

Article (9)

General Provisions

1. The Approved Standard Specifications indicated in the Annex attached to this Resolution shall be deemed mandatory for application in UAE. This Annex also shall be deemed an integral part thereof.
2. The Ministry shall be responsible for receiving and studying requests concerning registering the Product and granting it the Conformity Certificate in accordance with the provisions of this Resolution. Also, the Ministry may delegate any of the Competent Bodies or appoint an acceptable Conformity Assessment Body to assess the Product conformity, in accordance with the Cabinet Resolution concerning the UAE Law for the Control of Conformity Assessment Bodies.
3. This Resolution shall not prevent the inspectors of the Competent Authorities from controlling and Sampling to conduct checks on the Product in implementation of other Legislation in force in UAE.
4. The Relevant Parties subject to the provisions of this Resolution shall fully cooperate with the Ministry and the Competent Bodies and provide the information required to implement the provisions of this Resolution.
5. The Minister may amend any of the Standard Specifications contained in the Annex attached to this Resolution or approve any other Standard Specification required for the implementation of this Resolution, in accordance with the Legislation in force in this regard.
6. Should any situation arises that cannot be dealt with under the provisions of this Resolution, or should any dispute arises in the interpretation or application of this Resolution, such situation shall be referred to the Minister or whomever he delegates to issue the Resolution he deems appropriate concerning such situation or dispute by which the public interest is fulfilled.

Article (10)

Violations and Sanctions

1. Without prejudice to any penalty or procedure stipulated in any Legislation in force in UAE, should any of the provisions of Articles (3), (4), (5) and (8) of this Resolution is violated, the Ministry or the Competent Body, as the case may be, may impose one or more of the following administrative sanctions:

a. Coordinating with the Licensing Authority to cancel the commercial license of the Violating Supplier; and
b. Charging the Violator with the expenses and costs of removing and addressing the damages resulting from the violation in the event that he does not remove or address it.

2. In the event that the Ministry or the Competent Body, as the case may be, is not able to specify who is responsible for the Product non-conformity with this Resolution requirements, the Violator shall be deemed responsible for the non-conformity unless it is proven otherwise.

Article (11)

Grievance Procedures

1. Grievances may be filed against Resolutions issued pursuant to the provisions of Article (10) of this Resolution, provided that:
   a. The grievance is submitted to the Minister or the Competent Body Head or whoever they delegate in accordance with the procedures specified by the Ministry or the Competent Body, as the case may be, within a period not exceeding (14) working days as of the date on which the Violator is notified of the Resolution he wishes to submit a grievance thereon; and
   b. The necessary documents explaining the grievance reason are attached.
2. The Minister or the Competent Body Head or whoever they delegate shall issue the Resolution he deems appropriate concerning the grievance submitted in accordance with the provisions of this Article within a period not exceeding (25) working days as of its submission date. Also, the Resolution issued in this regard shall be deemed final, and the grievance shall be considered rejected in the event that no action is taken during the period specified in this Clause.

Article (12)

Repeals

Any provision that violates or contradicts the provisions of this Resolution shall be repealed.

Article (13)

Transitional Provisions

The Supplier who launch a Product in the market before this Resolution is published and shall be

granted a period not exceeding one calendar year as of the date of publishing this Resolution in the Official Gazette to regularize such Product in accordance with the provisions of this Resolution.

Article (14)

Publication and Enforcement of Resolution

This Resolution shall be published in the Official Gazette and shall be enforced as of the day following the date of its publication.

Mohamed bin Rashid Al Maktoum

Prime Minister

On: 02 Jumada al-Awwal 1442 A.H.

Corresponding to: December 17, 2020, A.D

Annex Attached to Cabinet Resolution No. (83) of 2020 Regarding the UAE System for Personal Health Protection Products

No.	Product	Technical Requirements	Approved Standard Specification
1	أقنعة الوجه الطبية Medical Face Masks	– Bacterial filtration efficiency (BFE) – Breathability (Differential pressure) – Splash resistance – Microbial cleanliness (Bioburden) – Materials and Construction	UAE.S EN 14683 (UAE.S ASTM F2100)
2	أقنعة الوجه ذات الفلتر المنقي Half Filtered Face Mask	– Total inward leakage – Penetration of filter material – Breathing resistance – Particle Filtration – Compatibility with skin	UAE.S EN 149
3	أقنعة الوجه غير الطبية (المصنعة من النسيج) Non-Medical "community" Face Mask (made from textile)	– pH – Formaldehyde – Heavy metals (Cadmium, Copper, Lead, Nickel)	UAE.S 1956
4	القفازات الو اقية Protective Gloves	– Bacteria, Fungi penetration Testing – Protection against Virus	UAE.S ISO 374-2

No.	Product	Technical Requirements	Approved Standard Specification
5	القفازات الطبية Medical gloves	– freedom from holes – Shelf Life and Resistance to degradation – Pack Integrity (for sterile gloves)	EN 455-Part 1 EN 455-Part 4
6	الملابس الواقية Protective clothing	– Resistance to Penetration by blood/body fluids. – Resistance to penetration by viruses. – Resistance to penetration by bacteria. – Resistance to penetration by biologically contaminated aerosols. – Resistance to penetration by contaminated dust.	EN 14126
7	واقيات العين الشخصية Personal eye-protection (Face shield and Goggles)	– Protection against droplets and splashes of liquids – General construction – Materials	EN 166
8	الأغطية والعبايات الجراحية (Surgical drapes and gowns)	– Resistance to microbial penetration – cleanliness microbial/bioburden – Liquid penetration	EN 13795 - part 1

No.	Product	Technical Requirements	Approved Standard Specification
		– Tensile strength – Bursting strength	
9	الأغطية والعبايات الجراحية (Clean air suits)	– Resistance to microbial penetration – cleanliness microbial/bioburden	EN 13795 – part 2
10	المعقمات والمطهرات الكيميائية chemical disinfectants and antiseptics	– Disinfecting efficiency (antimicrobial efficacy) – Evaluation of fungicidal or yeasticidal activity – Evaluation of virucidal activity in the medical area	UAE.S EN 1276 EN 1650 EN 14476:2013+A2
11	طلاء الأسطح المضادة للفيروسات Anti-microbial surface coating	– Measuring antiviral activity	ISO 21702

Notes:

- Detergent products, cosmetics, and personal care products shall not be subject to the technical requirements stipulated in item (10) of the Annex.
- The technical requirement specified in item (10) of the Annex concerning the Evaluation of virucidal activity shall be met only if antiviral claims are made for the product.
- Reference is made to other international standard specifications not referred to in the Annex for the purpose of ensuring that the product's compliance with the technical requirements set out therein after their acceptance and approval by the Ministry.