APPLICATION FOR EU TYPE EXAMINATION (Module B)
ANNEX V Clause 3. REGULATION (EU) 2016/425

Applicant name	Guangzhou shufang Medical Instruments Co.,Ltd.		
As *Read point (4) of this document*	Manufacturer		
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Name of authorized representative in Europe			
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As legal representative of the company
Position:

I request the EU Type Examination for PPE according to the Regulation (EU) 2016/425, described below:

Product Name / Reference	KN95 PROTECTIVE MASK
Made in:	China
Sizes:	
Quantity of samples provided:	100pcs
Applicable EN standards, international testing standards or other requirements. (In case of partially applied harmonized standards, the parts that have been applied will be specified in the documentation).	

Declares that:

- The same application has not been lodged with any other notified body.
- Knows and complies with Regulation (EU) 2016/425 in its entire contents, as well as Chapter II, so that, together with this application, the technical documentation described in Annex III to the Regulation(2) is provided.
- That together with this request one or several samples of the PPE representative of the intended production are submitted, committing me to submit the requested request by the notified body if it requests more samples if they are necessary to carry out the test program (1).
- I will inform the Notified Body in possession of the technical documentation relating to the EU-type examination certificate of all modifications of the approved type and of any modifications of the technical documentation which may affect the conformity of the PPE with the essential health and safety requirements or the conditions of validity of the certificate (such modifications will require additional approval in the form of a supplement to the original EU type-examination certificate).
- The Notified Body of AITEX ensures that it has an appeal procedure, whereby the applicant, upon request, can challenge the result of a conformity assessment.

(1) In the case of mass-produced PPE where each unit is adapted to suit a particular user, representative samples of the various users will be provided, and in the case of PPE produced as an individual unit to meet Specific needs of a particular user, a basic model will be provided.

(2) Together with this application, the following documents are provided:

List of technical documentation	Name of the document and date of issue	Indicate with X if provided
Technical Documentation (3).		X
User instructions		X
Example of labelling and other marking claimed in PPE.		X
Drawings and schemes for the design and manufacture of PPE and its components, sub-assemblies and circuits.		X
List of materials included in the PPE		X
Other documents.		X

(3) See document on technical documentation.

And understand and have been informed that:

- (4) According to Article 12 of Regulation (EU) 2016/425: An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and he shall be subject to the obligations of the manufacturer set out in Article 8 where he places PPE on the market under his name or trademark or modifies PPE already placed on the market in such a way that compliance with this Regulation may be affected.
- The certificate may be withdrawn if misuse is discovered. For example, failure to pay invoices for certification support testing, and / or conformity assessment, falsification of a certificate or misleading use of the certificate in advertising will be considered as an omission. The withdrawal together with the reason, will be delivered in writing.
- The Notified Body of Aitex is designated by the number 0161. The manufacturer can only refer to that number, in documents, that exclusively fit its content as evaluated by the Notified Body of Aitex.
- Only the certificates issued by the Notified Body of AITEX, containing the original handwritten signature or the electronic signature, issued by the Technical Direction will be recognized.
- Due to the duration of the tests, the tests will start to be carried out in parallel in all the laboratories, so that in case of not complying with the parameters and not being able to certify, the customer will pay all the tests performed so far.
- Otherwise, the customer must specify the order of execution of the tests, and therefore the delivery period will be extended according to the same.

- The signature of this application form constitutes the legally enforceable Certification Agreement, whereby the applicant with sufficient charge and authority to request the evaluation of the conformity and certification of their products, undertakes to comply with all obligations defined for manufacturers and / or economic agents in the framework of the activities carried out, defined in the current legislation of application (Regulation EU No. 2016/425 regarding personal protective equipment (PPE), as well as in point 4.1.2. ISO / IEC 17065:2012. The obligations on the part of the client and the Certification Body are available at the link: https://www.aitex.es//personal-protection-equipment-certificate/?lang=en

Date: 2020-05-08

Name, surname and title:

Authorized Signature and Company Seal: