

Test Report No.: 178144036a 001f

Page 1 of 5

Client : Anhui Forestwind Co.,Ltd**Contact Information** : Daxin Industrial Park,Taihe Town,Fuyang City,Anhui Province**Contact Person** : Cheng Fei**Sample Description As Declared :**

No. Of Sample : One(1)
Product Description : Medical protective clothing(non-sterilization)
Lot.No/Batch Code : 20200830
Colour : Blue
Manufactuer name : Anhui Forestwind Co.,Ltd.
Test standard : EN 13795-2:2019 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits
Test type : Partial test
Test Performed : Selected Test(s) As Requested By Applicant

Applicant's Provided Care Instruction/Label :

Sample obtaining method: Sending by customer
Sample Receiving date: 2020-09-11
Test Period: 2020-09-11 to 2020-09-25

For and on behalf of
TÜV Rheinland / CCIC (Qingdao) Co., Ltd.

2020-09-25

Assistant manager

Date

Name/Position

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

Conclusion
M001

Microbial Penetration-Dry^	P
Particle Release^	P
Cleanliness Microbial /Bioburden^	P
Bursting Strength-Dry ^	P
Tensile Strength-Dry ^	P

Note : P = Pass

= No Comment

N/A = Not Applicable

^=Indicates that the test is sub-contracted to a laboratory which complies with the requirement of ISO/IEC 17025:2017.

F = Fail

- = Did Not Perform

* = See Remark

Material list

Material No.	Material	Color	Location
M001	Whole Product	Blue	Medical protective clothing(non-sterilization)

1. Microbial Penetration-Dry[^]

Test method : EN ISO 22612:2005

<u>M001</u>	<u>Requirement</u>
<1CFU	≤100 CFU

Remark: Including seam.

2. Particle Release[^]

Test method : EN ISO 9073-10:2004

<u>M001</u>	<u>Requirement</u>
2.15 log ₁₀ (Lint Count)	≤4.0 log ₁₀ (Lint Count)

Remark: Including seam.

3. Cleanliness Microbial /Bioburden[^]

Test method : EN ISO 11737-1:2018

<u>M001</u>	<u>Requirement</u>
69 CFU/100cm ²	≤100 CFU/100cm ²

Remark: Including seam.

4. Bursting Strength–Dry ^

Test method : EN ISO 13938-1: 2019

	<u>M001</u>	<u>Requirement</u>
-Fabric	182 kPa	≥40 kPa
-Seam	280 kPa	≥40 kPa

5. Tensile Strength–Dry ^

Test method : EN 29073-3:1992

	<u>M001</u>	<u>Requirement</u>
-Fabric		≥20N
Lengthwise	122.4N	
Widthwise	62.8N	
-Seam	65.9N	≥20N

Sample Photo



- END -

General Terms and Conditions of Business of TÜV Rheinland in Greater China

<p>1. Scope</p> <p>1.1 These General Terms and Conditions of Business of TÜV Rheinland in Greater China ("GTBCB") is made between the client and one or more member entities of TÜV Rheinland in Greater China as applicable as the case may be ("TÜV Rheinland"). The Greater China hereof refers to Mainland China, Hong Kong and Taiwan. The client hereof includes:</p> <p>(i) a natural person capable to form legally binding contracts under the applicable laws who concludes the contract not for the purpose of a daily use;</p> <p>(ii) the incorporated or unincorporated entity duly organized, validly existing and capable to form legally binding contracts under the applicable law.</p> <p>1.2 The following terms and conditions apply to agreed services including consultancy services, information, deliveries and similar services as well as ancillary services and other secondary obligations within the scope of contract performance.</p> <p>1.3 Any standard terms and conditions of the client of any nature shall not apply and shall hereby be expressly excluded. No standard contractual terms and conditions of the client shall form part of the contract even if TÜV Rheinland does not explicitly object to them.</p> <p>1.4 In the context of an ongoing business relationship with the client, this GTBCB shall also apply to future contracts with the client without TÜV Rheinland having to refer to them separately in each individual case.</p> <p>2. Quotations</p> <p>Unless otherwise agreed, all quotations submitted by TÜV Rheinland can be changed by TÜV Rheinland without notice prior to its acceptance and confirmation by the other party.</p> <p>3. Coming into effect and duration of contracts</p> <p>3.1 The contract shall come into effect for the agreed terms upon the quotation letter of TÜV Rheinland or a separate contractual document being signed by both contracting parties, or upon the works requested by the client being carried out by TÜV Rheinland. If the client instructs TÜV Rheinland without receiving a quotation from TÜV Rheinland (quotation), TÜV Rheinland is, in its sole discretion, entitled to accept the order by giving written notice of such acceptance (including notice via electronic means) or by performing the requested work.</p> <p>3.2 The contract term starts upon the coming into effect of the contract in accordance with article 3.1 and shall continue for the term agreed in the contract.</p> <p>3.3 If the contract provides for an extension of the contract term, the contract term will be extended by the term provided for in the contract unless terminated in writing by either party with a six-week notice prior to the end of the contractual term.</p> <p>4. Scope of services</p> <p>4.1 The scope and type of the services to be provided by TÜV Rheinland shall be specified in the contractually agreed service scope of TÜV Rheinland by both parties. If no such separate service scope of TÜV Rheinland exists, then the written confirmation of order by TÜV Rheinland shall be decisive for the service to be provided.</p> <p>4.2 The agreed services shall be performed in compliance with the regulations in force at the time the contract is entered into.</p> <p>4.3 TÜV Rheinland is entitled to determine, in its sole discretion, the method and nature of the assessment unless otherwise agreed in writing or if mandatory provisions require a specific procedure to be followed.</p> <p>4.4 An execution of the work there shall be no simultaneous assumption of any guarantee of the correctness (proper quality) and working order of either tested or examined parts nor of the installation as a whole and its upstream and/or downstream processes, installations, use and application in accordance with regulations, nor of the systems which the installation is based on. In particular, TÜV Rheinland shall assume no responsibility for the construction, selection of materials and assembly of installations examined, nor for their use and application in accordance with regulations, unless these questions are expressly covered by the contract.</p> <p>4.5 In the case of inspection work, TÜV Rheinland shall not be responsible for the accuracy or checking of the safety programmes or safety regulations on which the inspections are based, unless otherwise expressly agreed in writing.</p> <p>4.6 If mandatory legal regulations and standards or official requirements for the agreed service scope change after conclusion of the contract, with a written notice to the client, TÜV Rheinland shall be entitled to additional remuneration for resulting additional expenses.</p> <p>4.7 The services to be provided by TÜV Rheinland under the contract are agreed exclusively with the client. A contract of third parties with the services of TÜV Rheinland, as well as making available of and justifying confidence in the work results (test reports, test results, expert reports, etc.) is not part of the agreed services. This also applies if the client passes on work results - in full or in extracts - to third parties in accordance with clause 11.4.</p> <p>5. Performance period/dates</p> <p>5.1 The contractually agreed periods/dates of performance are based on estimates of the work involved which are provided in line with the details provided by the client. They shall only be binding if being confirmed as binding by TÜV Rheinland in writing.</p> <p>5.2 If binding periods of performance have been agreed, these periods shall not commence unless the client has submitted all required documents to TÜV Rheinland. Articles 5.1 and 5.2 also apply, even without express approval by the client, to all extensions of agreed periods/dates of performance not caused by TÜV Rheinland.</p> <p>5.3 TÜV Rheinland is not responsible for a delay in performance, in particular if the client has not fulfilled his duties to cooperate in accordance with clause 6.1 or has not done so in time and, in particular, has not provided TÜV Rheinland with all documents and information required for the performance of the services as specified in the contract.</p> <p>5.4 If the performance of TÜV Rheinland is delayed due to unforeseeable circumstances such as force majeure, strikes, business disruptions, governmental regulations, transport obstacles, etc. TÜV Rheinland is entitled to postpone performance for a reasonable period of time which corresponds at least to the duration of the hindrance plus any time period which may be required to resume performance.</p> <p>6. The client's obligation to cooperate</p> <p>6.1 The client shall guarantee that all cooperation required on its part, its agents or third parties will be provided in good time and at no cost to TÜV Rheinland.</p> <p>6.2 Design documents, supplies, auxiliary staff, etc. necessary for performance of the services shall be made available free of charge by the client. Moreover, collaborative action of the client must be undertaken in accordance with legal provisions, standards, safety regulations and accident prevention instructions. And the client represents and warrants that:</p> <p>a) it has required statutory qualifications;</p> <p>b) the product, service or management system to be certified complies with applicable laws and regulations; and</p> <p>c) it doesn't have any illegal and dishonest behaviours or is not included in the list of Enterprises with Serious Illegal and Dishonest Acts of People's Republic of China.</p> <p>If the client breaches the aforesaid representations and warranties, TÜV Rheinland is entitled to immediately terminate the contract/order without prior notice and if it withdraws the issued testing report/certificates if any.</p> <p>6.3 The client shall bear any additional cost incurred on account of work having to be redone or being delayed as a result of late, incorrect or incomplete information provided by or lack of proper cooperation from the client. Even where a fixed or maximum price is agreed, TÜV Rheinland shall be entitled to charge extra fees for such additional expense.</p> <p>7. Prices</p> <p>7.1 If the scope of performance is not laid down in writing when the order is placed, invoicing shall be based on costs actually incurred. If no price is agreed in writing, invoicing shall be made in accordance with the price list of TÜV Rheinland valid at the time of performance.</p> <p>7.2 Unless otherwise agreed, work shall be invoiced according to the progress of the work.</p> <p>7.3 If the execution of an order extends over more than one month and the value of the contract or the agreed fixed price exceeds €2,500.00 or equivalent value in local currency, TÜV Rheinland may demand payments on account or in instalments.</p> <p>8. Payment terms</p> <p>8.1 All invoice amounts shall be due for payment without deduction on receipt of the invoice. No discounts and rebates shall be granted.</p> <p>8.2 Payments shall be made to the bank account of TÜV Rheinland as indicated on the invoice, stating the invoice and client numbers.</p> <p>8.3 In cases of default of payment, TÜV Rheinland shall be entitled to claim default interest at the applicable short term loan interest rate publicly announced by a reputable commercial bank in the country where TÜV Rheinland is located. At the same time, TÜV Rheinland reserves the right to claim further damages.</p> <p>8.4 Should the client default in payment or in spite of a dispute being granted a reasonable grace period, TÜV Rheinland shall be entitled to cancel the contract, withdraw the certificate, claim damages for non-performance and refuse to continue performance of the contract.</p> <p>8.5 The provisions set forth in article 8.4 shall also apply in cases involving returned cheques, cessation of payment, commencement of insolvency proceedings against</p>	<p>the client's assets or assets in which the commencement of insolvency proceedings has been demanded due to lack of assets.</p> <p>8.6 The invoices of TÜV Rheinland shall be submitted in writing within two weeks of receipt of the invoice.</p> <p>8.7 TÜV Rheinland shall be entitled to demand appropriate advance payments.</p> <p>8.8 TÜV Rheinland shall be entitled to raise its fees at the beginning of a month if overheads and/or purchase costs have increased. In this case, TÜV Rheinland shall notify the client in writing of the rise in fees. This notification shall be made one month prior to the date on which the rise in fees shall come into effect (period of notice of changes in fees). If the rise in fees remains under 5% per contractual year, the client shall have the right to terminate the contract. If the rise in fees exceeds 5% per contractual year, the client shall be entitled to terminate the contract by the end of the period of notice of changes in fees. If the contract is not terminated, the changed fees shall be deemed to have been agreed upon by the time of expiry of the notice period.</p> <p>8.9 Only legally established and undisputed claims may be offset against claims by TÜV Rheinland.</p> <p>9. Acceptance of work</p> <p>9.1 Any part of the work result ordered which is complete in itself may be presented by TÜV Rheinland for acceptance as an instalment. The client shall be obliged to accept it immediately.</p> <p>9.2 If acceptance is required or contractually agreed in an individual case, this shall be deemed to have taken place two (2) weeks after completion and handover of the work, unless the client refuses acceptance in the period stating at least one fundamental breach of contract by TÜV Rheinland.</p> <p>9.3 The client is not entitled to refuse acceptance due to insignificant breach of contract by TÜV Rheinland.</p> <p>9.4 If acceptance is excluded according to the nature of the work performance of TÜV Rheinland, the completion of the work shall take its place.</p> <p>9.5 If the client was unable to make use of the time windows provided for within the scope of a certification procedure, the resulting performance by TÜV Rheinland and the certificate is therefore to be withdrawn (e.g. performance of surveillance audits). TÜV Rheinland is entitled to immediately charge a lump-sum compensation of 10% of the order amount as compensation for its expenses. The client reserves the right to prove that the TÜV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above lump sum.</p> <p>9.6 Insofar as the client has undertaken in the contract to accept services, TÜV Rheinland shall also be entitled to charge lump-sum damages in the amount of 10% of the order amount as compensation for expenses if the service is not called within one year after the order has been accepted in writing. The client reserves the right to prove that TÜV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above mentioned lump sum.</p> <p>10. Confidentiality</p> <p>10.1 For the purpose of these terms and conditions, "confidential information" means all information, documents, images, drawings, know-how, data, samples and project documentation which one party (the "disclosing party") hands over, transfers or otherwise discloses to the other party (the "receiving party"), and the confidential information created during the performance of TÜV Rheinland and the holding, product testing data, defects, conformity to the technical standard and related reports. Confidential information also includes paper copies and electronic copies of such information. Confidential information is expressly not the data and know-how collected, compiled or otherwise obtained by TÜV Rheinland (non-personal) within the scope of the provision of services by TÜV Rheinland. The client reserves the right to store, use, further develop and pass on the data obtained in connection with the provision of services for the purposes of developing new services, improving services and analysing the provision of services.</p> <p>10.2 The disclosing party shall mark all confidential information disclosed in written form as confidential before passing it to the receiving party. The same applies to confidential information transmitted by e-mail. If confidential information is disclosed orally, the receiving party shall be expressly informed in advance and the disclosing party shall confirm in writing the confidentiality nature of the information within five working days of oral disclosure. If the disclosing party fails to do so within the stipulated period, the receiving party shall not take any confidentiality obligations hereafter towards such information.</p> <p>10.3 All confidential information which the disclosing party transmits or otherwise discloses to the receiving party and which is created during performance of work by TÜV Rheinland:</p> <p>a) may only be used by the receiving party for the purposes of performing the contract, unless expressly otherwise agreed in writing by the disclosing party;</p> <p>b) may not be copied, distributed, published or otherwise disclosed by the receiving party, unless this is necessary for fulfilling the purpose of the contract or TÜV Rheinland is required to pass on confidential information, inspection reports or documentation to the government authorities, judicial court, accreditation bodies or third parties that are involved in the performance of the contract;</p> <p>c) must be treated by the receiving party with the same level of confidentiality as the receiving party uses to protect its own confidential information, but never with a lesser level of confidentiality than what is reasonably required;</p> <p>d) the receiving party may disclose any confidential information received from the disclosing party only to those of its employees who need this information to perform the services required for the contract. The receiving party undertakes to oblige these employees to observe the same level of secrecy as set forth in this confidentiality clause.</p> <p>10.4 Information for which the receiving party can furnish proof that:</p> <p>a) it was generally known at the time of disclosure or has become general knowledge without violation of this confidentiality clause by the receiving party; or</p> <p>b) it was disclosed to the receiving party by a third party entitled to disclose this information; or</p> <p>c) the receiving party already possessed this information prior to disclosure by the disclosing party; or</p> <p>d) the receiving party developed it itself, irrespective of disclosure by the disclosing party, shall be deemed to constitute "confidential information" as defined in this confidentiality clause.</p> <p>10.5 All confidential information shall remain the property of the disclosing party. The receiving party hereby agrees to immediately (i) return all confidential information, including all copies, to the disclosing party, and/or (ii) on request by the disclosing party, to destroy all confidential information, including all copies, and confirm the destruction of this confidential information to the disclosing party in writing, at any time if so requested by the disclosing party but at the latest and without special request after termination or expiry of the contract. This shall extend to include reports and certificates prepared for the client solely for the purpose of fulfilling the obligations under the contract, which shall remain with the client. However, TÜV Rheinland is entitled to make file copies of such reports, certificates and confidential information that forms the basis for preparing these reports and certificates in order to evidence the correctness of its results and for general documentation purposes required by laws, regulations and the requirements of working procedures of TÜV Rheinland.</p> <p>10.7 From the start of the contract and for a period of three years after termination or expiry of the contract, the receiving party undertakes to maintain the secrecy of all confidential information and shall not disclose this information to any third parties or use it for itself.</p> <p>11. Copyrights and rights of use, publications</p> <p>11.1 TÜV Rheinland shall retain all exclusive copyrights in the reports, expert reports/opinions, test reports/results, results, calculations, presentations etc. prepared by TÜV Rheinland, unless otherwise agreed by the parties in a separate agreement.</p> <p>11.2 As the owner of the copyrights, TÜV Rheinland is free to grant others the right to use the work results for individual or all types of use ("right of use"). The client receives a simple, unlimited, non-transferable, non-sublicensable right of use to the contents of the work results produced within the scope of the contract, unless otherwise agreed by the parties in a separate agreement. The client may only use such reports, expert reports/opinions, test reports/results, results, calculations, presentations etc. prepared within the scope of the contract for the contractually agreed purpose.</p> <p>11.3 The transfer of right of use of the generated work results regulated in clause 11.2 of the GTBCB is subject to full payment of the remuneration agreed in favour of TÜV Rheinland.</p> <p>11.4 The client may use the work results for individual or all types of use ("right of use") for the work results in full unless TÜV Rheinland has given its prior written consent to the partial passing on of work results for advertising purposes or any further use of the work results beyond the scope regulated in clause 11.2 needs the prior written approval of TÜV Rheinland in each individual case.</p> <p>11.5 Any publication or duplication of work results of such reports, certificates and confidential information may revoke a once given approval according to clause 11.5 at any time without stating reasons. In this case, the client is obliged to stop the transfer of the work results immediately at his own expense and, as far as possible, to withdraw publication.</p> <p>11.7 The consent of TÜV Rheinland to publication or duplication of the work results does not entitle the client to use the corporate logo, corporate design or test/certification mark of TÜV Rheinland.</p> <p>12. Liability of TÜV Rheinland</p> <p>12.1 Irrespective of the legal basis, to the fullest extent permitted by applicable law, in the event of a breach of contractual obligations or tort, the liability of TÜV Rheinland for all damages, losses and reimbursement of expenses caused by TÜV Rheinland, its legal representatives and/or employees shall be limited to: (i) in the case of a contract with a fixed overall fee, three times the overall fee for the entire contract; (ii) in the case of a contract for annual recurring services, the agreed annual fee; (iii) in the case of a contract expressly charged on a time and material basis, a maximum of 20,000 Euro or equivalent amount in local currency; and (iv) in the case of a framework agreement that provides for the possibility of placing individual orders, three times of the fee for the individual order under which the damages or losses have occurred. Notwithstanding the above, in the event that the total and accumulated liability calculated according to the foregoing provisions exceeds 2.5 Million Euro or</p>	<p>equivalent amount in local currency, the total and accumulated liability of TÜV Rheinland shall be only limited to and shall not exceed the said 2.5 Million Euro or equivalent amount in local currency.</p> <p>12.2 The limitation of liability according to article 12.1 above shall not apply to damages and/or losses caused by malice, intent or gross negligence on the part of TÜV Rheinland or its vicarious agents. Such limitation shall not apply to damages for a person's death, physical injury or illness.</p> <p>12.3 In cases involving a fundamental breach of contract, TÜV Rheinland will be liable even where minor negligence is involved. For this purpose, a "fundamental breach" is a breach of a material contractual obligation, the performance of which permits the due performance of the contract. Any claim for damages for a fundamental breach of contract shall be limited to the amount of damages reasonably foreseeable as a possible consequence of such breach of contract at the time of the breach (reasonably foreseeable damages), unless any of the circumstances described in article 12.2 applies.</p> <p>12.4 TÜV Rheinland shall not be liable for the acts of the vicarious made available by the client to support TÜV Rheinland in the performance of its services under the contract, unless such personnel made available is regarded as vicarious agent of TÜV Rheinland. If TÜV Rheinland is not liable for the acts of the personnel made available by the client under the foregoing provision, the client shall indemnify TÜV Rheinland against any claims made by third parties arising from or in connection with such personnel's acts.</p> <p>12.5/12.6/12.7/12.8/12.9/12.10/12.11/12.12/12.13/12.14/12.15/12.16/12.17/12.18/12.19/12.20/12.21/12.22/12.23/12.24/12.25/12.26/12.27/12.28/12.29/12.30/12.31/12.32/12.33/12.34/12.35/12.36/12.37/12.38/12.39/12.40/12.41/12.42/12.43/12.44/12.45/12.46/12.47/12.48/12.49/12.50/12.51/12.52/12.53/12.54/12.55/12.56/12.57/12.58/12.59/12.60/12.61/12.62/12.63/12.64/12.65/12.66/12.67/12.68/12.69/12.70/12.71/12.72/12.73/12.74/12.75/12.76/12.77/12.78/12.79/12.80/12.81/12.82/12.83/12.84/12.85/12.86/12.87/12.88/12.89/12.90/12.91/12.92/12.93/12.94/12.95/12.96/12.97/12.98/12.99/13.00</p>
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La notificación se ha realizado correctamente.

Datos de registro	
Código de Expediente:	RPS/2313/2020
Fecha Registro:	30/09/2020 16:06:02
Nº registro General:	RPS/2313/2020
Oficina:	ETEL
Nº registro Oficina:	RPS/2313/2020

Registro de Responsables de Productos Sanitarios - RPS/2313/2020

Datos de la notificación

Datos de registro

Nº Registro	<input type="text" value="RPS/2313/2020"/>	Fecha Registro	<input type="text" value="30/09/2020"/>
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Datos del Responsable

Tipo de Responsable (*)	<input type="text" value="Rep. Autorizado"/>	Tipo de entidad	<input type="text" value="Empresa"/>
CIF (*)	<input type="text" value="B93316149"/>	Nombre (*)	<input type="text" value="CMC MEDICAL DEVICES & DRUGS S.L."/>
Dirección (*)	<input type="text" value="C/ HORACIO LENGU Nº 18"/>		
Localidad (*)	<input type="text" value="MÁLAGA"/>		
Provincia (*)	<input type="text" value="Málaga"/>	CP (*)	<input type="text" value="29006"/>
Teléfono (*)	<input type="text" value="951214054"/>	Fax	<input type="text"/>
e-mail (*)	<input type="text" value="info@cmmedicaldevices.com"/>	Web	<input type="text"/>

Datos del Fabricante

Nombre o Razón Social (*)	<input type="text" value="ANHUI FORESTWIND CO., LTD."/>		
Dirección (*)	<input type="text" value="Daxin Industrial Park,Taihe Town,Fuyang City,Anhui Province,China"/>		
Localidad (*)	<input type="text" value="Anhui"/>		
País (*)	<input type="text" value="República Popular China"/>	CP	<input type="text"/>
Teléfono (*)	<input type="text" value="13655695161"/>	Fax	<input type="text"/>
e-mail (*)	<input type="text" value="forrest@ahforestwind.com"/>	Web	<input type="text"/>

Relación de Productos

Listado de Productos Sanitarios

Se encontro una fila.

Listado de Productos Sanitarios			
Nombre Comercial	Tipo de Producto	Estado del producto	Acción
MEDICAL PROTECTIVE CLOTHING (NON-STERILIZATION)	Clase I	Primera Comunicación	

EC REP CERTIFICATE



CMC MEDICAL DEVICES & DRUGS SL NO. CMC/CE/2020/30092020.14

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized
Representative of

ANHUI FORESTWIND CO., LTD.

Daxin Industrial Park, Taihe Town, Fuyang City, Anhui Province, China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/2313/2020**

Issued on: 30/09/2020

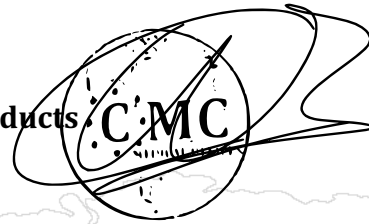
Valid until: 29/09/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE



ANNEX I Medical Device Products



Medical protective clothing (non-sterilization)

CE



AGREEMENT EC REP CMC MEDICAL DEVICES

This Agreement made on sept 30, 2020 between Anhui Forestwind Co., Ltd. in First Daxin Industrial Park, Taihe Town, Fuyang City, Anhui Province, China (hereinafter referred to as "COMPANY") and M/s CMC Medical Devices & Drugs S.L. located in C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain (hereinafter referred to as "Authorized Representative")

Have agreed as follows with regard to the handling of all products (hereinafter called "Products") manufactured by Company and sold to EU in order to comply to the requirements set out in the COUNCIL DIRECTIVE 93/42/EEC (MDD), Regulation (EU) 2017/745 (MDR) Concerning Medical Devices, or 98/79/EC (IVDD), Regulation (EU) 2017/746 (IVDR) concerning in vitro diagnostic medical devices (as per applicability) and latest version of "Guidelines on a Medical Devices Vigilance System".

Appointment

Company hereby appoints Authorized Representative, who accepts such appointment, as a representative for the "Business Area" and "Product Categories" set out in Appendix A. The responsibility of both parties is as stated hereafter. Service of European Authorized Representative cover the MDD 93/42/EEC on medical devices, or, IVDD 98/79/EC on in vitro diagnostic medical device. The service will cover the new Regulation (EU) 2017/745 (MDR) on medical devices, or, (EU)2017/746 (IVDR) on in vitro diagnostic medical devices and when this regulation take effect.

Claim Handling

Authorized Representative shall notify company about any received claims and any change of laws and regulations related to company's products set out in Appendix A. Company is the immediate responsible person for the claim handling and regulation compliance.

Accident Handling

On receiving information of an incident (accident), as defined in the 93/42/EEC (MDD), Regulation (EU) 2017/745 (MDR), or, 98/79/EC (IVDD), Regulation (EU) 2017/746 (IVDR) (as per applicability) and MEDDEV 2.12-1 "Guidelines on a Medical Devices Vigilance System", the following procedures shall be applied:

Authorized Representative shall notify occurrence of an incident in its business area to Company immediately upon receiving of incident.

Upon receiving information of any incident Company shall perform the necessary analysis of the situation immediately and send the incident report to Authorized Representative according to the requirements of latest version of "Guidelines on a Medical Devices Vigilance System". In that way Authorized Representative can submit the report



to the relevant Competent Authority as defined in the timescale of latest version of “Guidelines on a Medical Devices Vigilance System”.

If applicable, based on the report Company shall instruct Authorized Representative of the necessary countermeasures to be taken. Authorized Representative shall inform the relevant Competent Authority and customer as required in the countermeasure plan issued by Company.

Responsibilities on Technical Documentation:

- i. Company shall establish necessary procedures to prepare and maintain Technical Documentation including the Declaration of Conformity for the “Product Categories” set out in Appendix A to be able to comply with the MDD, IVDD, or MDR, IVDR requirements.
- ii. Company shall transfer the agreed Technical Documentation and Declaration of Conformity to Authorized Representative upon request.
- iii. Company shall have the responsibility to provide to Authorized Representative any additional documentation as required by the Competent Authority or Notified Body.
- iv. The authorized representative shall provide a copy of this agreement to the competent authority, upon request.

Instruction Manual (If applicable)

Company shall be responsible for the content of instruction (user’s) manuals, and shall ensure that English language instruction manuals are available to Authorized Representative. Company shall ensure that the required local language instruction manuals are provided to the customers.

Registration

The Authorized Representative shall register or notify the products set out in Appendix A to the Competent Authority of the member state in which he has his registered place of business.

Company shall have all data allowing for identification of concerned devices together with the label and the instruction for use available to authorized representative upon request by competent authority.

Tasks to be performed by Authorized Representative:

- i. Verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the company;
- ii. Keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and



- supplements, available for the competent authorities for a period of at least 10 years after the last device covered by the eu declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market;
- iii. Comply with the registration obligations laid down in, article 14 of 93/42/EEC (MDD), article 31 of Regulation (EU) 2017/745 (MDR), OR, article 10 of 98/79/EC (IVDD), article 28 of Regulation (EU) 2017/746 (IVDR) and verify that the company has complied with the registration obligations laid down in articles 27 and 29 of Regulation (EU) 2017/745 (MDR), OR, article 24 and 26 of Regulation (EU) 2017/746 (IVDR);
 - iv. In response to a request from a competent authority, provide that the competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official union language determined by the member state concerned.
 - v. Forward to the company any request by a competent authority of the member state in which the authorized representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;
 - vi. Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
 - vii. Terminate this agreement if the company acts contrary to its obligations under this regulation;
 - viii. Authorized representatives will have permanently and continuously at their disposal at least one person responsible for regulatory compliance (PRRC) who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union.

Obligations of Manufacturer Company:

- i. COMPANY must comply with all the requirements specified in Article 10 of Regulation (EU) 2017/745 (MDR), OR, article 10 of Regulation (EU) 2017/746 (IVDR) regarding general obligations of manufacturers.
- ii. COMPANY shall procure and maintain at all times during the term of this Agreement a Product liability insurance covering the products placed on the European market. This liability insurance should include "EAR" as well. This insurance, however, will not protect "EAR" against liability which results from its unauthorized Activities, wrongful or negligent acts of omission, or breach of this Agreement.
This agreement will not be valid if the manufacturer does not meet this requirement.

Other Obligations of Authorized Representative & Company:



- i. The authorized representative shall provide all documentation and information that a market surveillance authority may require for the purpose of market surveillance.
 - ii. The authorized representatives shall rescind his contract with the company if the latter does not provide him with the access to the necessary information.
 - iii. Company shall keep authorized representative informed in all matters that may be connected to the devices placed on the market in the EU. At the minimum, the exchange of information concerning paragraphs a) to c) hereunder shall be informed.
- a) Safeguard Clause
- i. “Where a Member State ascertains that any of the medical devices specified in Appendix A, when correctly used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service.” If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such measures to the company and advise the company as to the implications of this decision.
 - ii. When the Commission finds that national measures taken under the Safeguard Clause “are unjustified, it shall immediately so inform the Member State which took the measures and the company or authorized representative”. If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the company and advise the company as to the implications of this decision.
- b) Vigilance
- i. In case of an incident and If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the company and advise the company as to the implications of this decision.
 - ii. The company should ensure that the involved authorized representative is kept informed of incident reports and Field Safety Corrective Actions.
- c) Serious adverse events during clinical investigation, i.e. in the premarket phase
- i. According to Article 80 of Regulation (EU) 2017/745 (MDR) and article 76 of Regulation (EU) 2017/746 (IVDR), “all serious adverse events must be fully recorded and immediately notified to all Competent Authorities of the Member States in which the clinical investigation is being performed by the sponsor”.
 - ii. Authorized representative should inform the company of decisions of a Member State in respect of refusal or restriction of the placing the devices specified in Appendix A in the market.



(Appendix A)

Product list:

No	Name of device	UMDN Code	EDMA	Class
1	Medical protective clothing (non-sterilization)	15037	N/A	I

The following countries represent Authorized Representative's Business Area:

EUROPEAN COMMUNITY TERRITORY

Annual Fee: EC REP fee will be paid by ABmed (Shanghai) Medical Technology Co., Ltd to CMC Medical Devices & Drugs S.L

Validity of Agreement: This agreement shall stand valid from Sep.30, 2020 to Sep. 29, 2021. The Company shall apply for renewal of the agreement at least 30 days prior to expiry of this agreement.

Anhui Forestwind Co., Ltd.
Daxin Industrial Park, Taihe Town, Fuyang
City, Anhui Province, China
Tel: 13655695161
E-mail: forrest@ahforestwind.com

Authorized Signatory

China on Sep. 30, 2020

CMC MEDICAL DEVICES & DRUG
S.S.L. (EC REP AUTHORI
ZED REPRESENTATIVE)

Authorized Signatory

Spain on Sep. 30, 2020.

ANHUI FORESTWIND CO., LTD.

DAXIN INDUSTRIAL PARK, TAILIN ROAD, DAXIN TOWN, TAIHE CITY, ANHUI PROVINCE, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A)Non woven isolation gown: in blue

Style No. : FWIS02

Manufacturer : Anhui Forestwind Co.,Ltd

Supplier : Anhui Forestwind Co.,Ltd

Country of Origin : China

Country of Destination : United States, EUR

Sample Receiving Date : Aug 31, 2020

Testing Period : Aug 31, 2020 - Sep 09, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Test Performed : Selected test(s) as requested by applicant

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Nanjing Branch

Janice Xu.

Janice Xu (Account Executive)



SGS-CSTC Standards Technical Services Co., Ltd.
Nanjing Branch Textile Laboratory

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中国·南京·秦淮区永丰大道8号2幢1层 邮编: 210014 t (86-25) 84556406 f (86-25) 84553467 e sgs.china@sgs.com

Test Result

Abrasion Resistance

(EN ISO 12947-2:2016 (Modified); Martindale Abrasion & Pilling Tester, Pressure: 9kPa)

	Unit	(A)		
		#1	#2	#3
The quoted result	Rubs	8000	10000	14000

Tearing Strength

(ISO 9073-4:1997)

	Unit	(A)
Warp/Length Yarns Torn	N	41
Weft/Width Yarns Torn	N	36

Tensile Strength

(ISO 9073-3:1989)

	Unit	(A)
Warp/Length	N	66.9
Weft/Width	N	38.4

Water Resistance(Hydrostatic Head)

(EN ISO 811:2018; Hydrostatic Head; Rate of increase of water pressure: 60 cmH₂O/min, temp. of distilled water: 20°C, Face Side Facing Water)

(A)	No. 1	No. 2	No. 3	No. 4	No. 5	Average
<u>As Received</u> Water Column(mmH ₂ O)	1401	1357	1345	1334	1323	1352

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Sample Photo



End of Report

