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Dorota Metler
Data: 2021.02.12 10:06:22 EET

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Dokument podpisany przez
Dorota Metler
Data: 2021.01.20 08:35:30 EET

Jednorazowy kombinezon ochronny typ 5
Producent: Zhejiang Huaf Medical Equipment Co.Ltd.

Kombinezon ochronny wykonany jest z tkaniny laminowanej o gramaturze 70 g/m^2. Warstwa zewnętrzna pokryta jest folią polietylenową, natomiast warstwa wewnętrzna pokryta jest włóknem polipropylenowym posiadającym odporność na przenikanie czynników zakaźnych

Kombinezon ochronny wykonany został z lekkiego, oddychającego i niskopylącego materiału. Wyposażony w zamek błyskawiczny dla dodatkowego komfortu. Elastyczny pas, nogawki i nadgarstki zapewniają swobodę ruchów.

Właściwości i wykonanie:
- lekki i bardzo wytrzymały, obszerny krój,
- przepuszczalny dla powietrza i pary wodnej,
- wszystkie szwy szczelne,
- gładki i niezwilżany,
- antyelektrostatyczny,
- niepylący,
- odporny na przebijanie, rozdzieranie, pyły włókna i natrysk chemikaliów,
- zdolność zatrzymywania pyłów pomiędzy 1,0 a 5,0 nanometra wynosi 99,9%
- zapewnia ochronę biologiczną
- gumka w talii zapewniająca optymalne dopasowanie kombinezonu do ciała
- elastyczne pętelki na kciuki,
- ściągacze na rękawach, nogawkach i kapturze
- samoprzylepna osłona zamka błyskawicznego
- przyklejana osłona podbródka

Spełnia następujące wymagania:

- kombinezon ochronny typ 5 wg klasyfikacji zgodnie z normą EN 14605: 2005+A1:2009,
- rękawy z elastyczną silikonową taśmą zabezpieczającą,
- wykonany z materiału minimum 1 klasy palności,
- wykonany z barierowej włókniny polipropylenowej, bez zawartości lateksu, polietylenu i celulozy do procedur wysokiego ryzyka,
- szwy, połączenia trwałe i rozdzielne płaskie,
- zamek błyskawiczny kryty listwą,
- pakowany w indywidualne opakowanie
- oznakowany znakiem CE.

CE认证
CE Certification

华 福 HUAFU

Certyfikat CE

Certificate of Compliance

Application for
Medical Device Directive (MDD) 93/42/EEC.

This is to certify that the product(s):

Medical Coverall PPE Suits, Medical Coverall Isolation Gowns, Medical Shoe Covers, Medical / Surgical Face Masks, Medical Protective Clothing.

Manufactured by

Zhejiang Huafu Medical Equipment Co. Ltd.

No. 688, Xinxing 1st Road, 314200 Pinghu, Jiaxing, Zhejiang Province, People's Republic of China

has been assessed & found in accordance with the requirements of **MDD 93/42/EEC as amended by 2007/47/EC CLASS 1 (Non-Sterile) and CLASS 2 (Sterile)**.
QCC is non-notified certification body, issue this 'compliance certificate' after audit of manufacturer product(s) & technical file(s).
This certificate applies to the tested sample only not for whole production.
It's manufacturer sole responsibility to meet all the necessary conformity assessment activities according to **MDD 93/42/EEC** and related standards before placing them on the market & CE mark on the product(s).

Certificate No.	: **CE/017151/0620**
Original Certificate Date	: 12 - June - 2020
Issue Date	: 12 - June - 2020
Expiry Date	: 11 - June - 2023

To check this certificate status visit:
"http://uasl.uk.com/certifiedorganization.html"

Authorised Signature

For **Quality Control Certification**
UK Office: 1929, Chynoweth House, Trevissome Park, Truro-TR48UN, Cornwall, UK

Quality Control Certification accredited by UKAS, UK.
This certificate doesn't provide the certified organization with immunity from its legal obligations.
This certificate remains the property of QC Certification to whom it must be returned on request.

Deklaracja Zgodności

Declaration of conformity CE

Manufacturer:

Name: ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD
Address: 688 XINXING 1ST RD. 314200 PINGHU, JIAXING, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA
TEL: 0573-85963333 FAX: 0573-85963336

European Representative:

Name: Lotus NL B.V.
Address: Koningin Julianaplein 10 te Wet 2595AA, The Hague, Netherlands
Tel: +31(0)6171379
E-mail: peter@huafu.com

Product Name: Protective Clothing
Specification: 140(S), 145(M), 150(L), 155(XL), 160(XXL), 165(XXXL)

Specification	Height(cm)	Bust(cm)	Sleeve(cm)	Collar(cm)	Leg opening(cm)
140(S)	160-5	100	84	20	24
145(M)	165	105	85	20	24
150(L)	167.5	110	87	20	24
155(XL)	170	115	89	20	24
160(XXL)	172.5	120	91	20	24
165(XXXL)	175	125	93	20	24
Tolerance	±0.5	±2.5	±2.5	±0.5	±0.5

Intended use:
It is used for medical staff in medical institutions working to prevent the transmission of the virus from the patient to the medical staff with or in liquid.

Product Policy:
Risk Class of the Device: The medical device has been assigned to class 1 - rule 1 according to ANNEX VIII, Medical Device REGULATION (EU) 2017/745 consolidated version.

The product meets the provisions of Medical Device REGULATION (EU) 2017/745 which apply to them.

The medical device has been assigned to class 1 according to ANNEX VIII, Medical Device REGULATION (EU) 2017/745. It bears the mark

The product assessment has been designed and manufactured under a quality management system according to ANNEX IX of Medical Device REGULATION (EU) 2017/745

Following the procedure relating to the EC Declaration of Conformity set out in ANNEX IX of Medical Device REGULATION (EU) 2017/745.

This Declaration of conformity is valid in connection with the relevant document for the respective batch or produced devices.

The above-mentioned declaration of conformity is exclusively under the responsibility of

Company: ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
Address: 688 XINXING 1ST RD. 314200 PINGHU, JIAXING, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA

Jiaxing, 09-03-2020 — Place, date

Alan Wang, General Manager — Legally binding signature, Function

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer K. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 24 april 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Wei,

Graag bevestig ik hierbij de ontvangst op 9 april 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Zhejiang Huafu Medical Equipment Co.,Ltd met Europees gemachtigde Lotus NL B.V. onderstaand medisch hulpmiddel, vogdoelt in risicoklasse 1, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

Medical face mask(non-sterile),Protective clothing(non-sterile)
(geen merknaam) (NL-CA002-2020-50404)

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het – ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Het name mijzen wij u op de Nederlandse taaiers, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

Farmatec
Bezoekadres
Zuiderpoort
Kijkduin 20
2513 AP Den Haag
T 070 340 4040
http://www.farmatec.nl

Inlichtingen bij:
J.J. van de Velde
medische hulpmiddelen@farmatec.nl

Ons kenmerk:
CIBG 2020/1324

Bijlagen
-

Uw aanvraag
9 april 2020

Correspondentie uitsluitend richten aan het rechtspersoon met vermelding van de datum en het kenmerk van deze brief.

Pagina 1 van 2

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen beslisst betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Dhr. M.J. van de Velde

Pagina 2 van 2

浙江华福医用器材有限公司 Zhejiang Huafu Medical Equipment Co., Ltd.
浙江 · 平湖 浙江省平湖市新兴一路688号 No. 688 Xinxing 1st Road, Pinghu City, Zhejiang Province, 314200China.
0573-85963333 Http://www.huafuzj.com E-mail : sales@huafuzj.com

Form No. : FCLZJ200330158

Testing report

Applicant:*	Zhejiang Huafu Medical Equipment Co.,Ltd.
Contacts:*	/
Address:*	688 Xinxing 1st Rd., Pinghu, Jiaxing, Zhejiang Province, 314200 China
Sample Description:*	Portective clothing
Style No.:*	175
Application Date:	2020.03.23
Report Date:	2020.04.03

-The contents with "*" is provided by the client .

Test Conclusion： The sample has been tested and the tested items meet the requirements of BS EN 14126:2003/AC:2004

Authorized signature: Li Qingzheng

Hangzhou Mingfang Textile Testing Service Co., Ltd MFTS Inspection & Testing Service Test sealed

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Tel:400 883 4444 Email:zj@vip.zj.cn Web:www.mfzts.com

Form No. : FCLZJ200330158

EN 14126:2003/AC:2004			
Clause	Requirement + Test	Result - Remark	Verdict
4	Requirements		
4.1	Materials requirements		P
4.1.1	General		P
	If the care instructions indicate that the clothing can be cleaned and reprocessed at least five times, protectiveclothing materials shall be submitted to five cleaning and reprocessing cycles according to the manufacturer's care instructions before testing.		P
	If the care instructions specify a lower number of cleaning/reprocessing cycles, then materials shall be submitted to the number of cleaning/reprocessing cycles indicated.		P
	Unless otherwise stated in the relevant test procedure, the specimens shall be conditioned for at least 24 h inan atmosphere of (20 ± 2) °C and (65 ± 5) % relative humidity before testing. Tests shall be carried out in thesame atmosphere or within 5 min of removingthe sample from the conditioning atmosphere.		P
4.1.2	Mechanical and flammability requirements		P
	The materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.		P
4.1.3	Chemical requirements If protection against chemicals is claimed, the materials shall be tested and classified in accordance with thetest methods and performance classification system specified in the relevant clauses of prEN 14325.		P
4.1.4	Performance requirements against penetration by infective agents		P
4.1.4.1	Resistance to penetration by contaminated liquids under hydrostatic pressure When tested in accordance with ISO/FDIS 16603 and ISO/FDIS 16604 the material shall be classified according to the levels of performance given in Table 1, as obtained in the bacteriophage test (ISO/FDIS 16604). Table 1 —Classification of resistance to penetration by contaminated liquids under hydrostatic pressure (ISO/FDIS 16604)	Class 2 1.75 kpa	P

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		Class / Hydrostatic pressure at which the material passes the test 6 / 20 kPa 5 / 14 kPa 4 / 7 kPa 3 / 3,5 kPa 2 / 1,75 kPa 1 / 0 kPa[a] [a] this means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell		
4.1.4.2	Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.			P
	When tested in accordance with Annex A the material shall be classified according to the levels of performance given in Table 2. Table 2 —Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids Class / Breakthrough time, *t* min 6 / t>75 5 / 60<t≤75 4 / 45 < t ≤60 3 / 30 < t ≤ 45 2 / 15<t ≤ 30 1 / ≤ 15 min			P
4.1.4.3	Resistance to penetration by contaminated liquid aerosols When tested in accordance with ISO/DIS 22611 the material shall be classified according to the levels of performance given in Table 3. **Table 3 — Classification of resistance to penetration by contaminated liquid aerosols**			P

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		Class: 3 — Penetration ratio (log): log > 5 Class: 2 — Penetration ratio (log): 3 < log ≤ 5 Class: 1 — Penetration ratio (log): 1 < log ≤ 3		
4.1.4.4	Resistance to penetration by contaminated solid particles.			P
	When tested in accordance with ISO/DIS 22612 the material shall be classified according to the levels of performance given in Table 4. Table 4 —Classification of resistance to penetration by contaminated solid particles Class: 3 — Penetration (log cfu): ≤1 Class: 2 — Penetration (log cfu): 1 < log cf u ≤ 2 Class: 1 — Penetration (log cfu): 2 < log cfu ≤ 3			P
4.2	Performance requirements for seams, joins and assemblages Seams, joins and assemblages of protective clothing against infective agents shall fulfil the requirements specified in the relevant clauses of prEN 14325 Seam strength shall be classified according to 5.5 of prEN14325:2001.			P
4.3	Whole suit requirements Protective clothing against infective agents shall fulfil the relevant requirements of EN 340 and the whole suit requirements specified in the relevant standard for chemical protective clothing (see Table 5). The materials and design used shall not cause skin irritation nor have any adverse effect to health. Table 5 —Types of protective clothing against infective agents Type of dotting: type 1a, 1b, 1c, 2 — Relevant standard: EN 943-1 (EN 943-2 for ET Type of dotting: type 3 — Relevant standard: EN 466 Type of dotting: type 4 — Relevant standard: EN 465		No chemical protectiv e clothing	P

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		type 5 / prEN ISO 13982-1 type 6 / prEN 13034 partial body protection / EN 467		
5	Marking The clothing shall be marked in accordance with the applicable requirements of the relevant standard for chemical protective clothing. The marking of protective clothing against infective agents shall contain the following additional information: a) the number of this European Standard; b) the type of protective clothing, as specified in Table 5, with the suffix "-B", e.g. type 3-B; c) the pictogram "protection against biological hazard"		See label	P
6	Information supplied by the manufacturer The information for the user shall be worded clearly and unambiguously and be understandable by a trained person.		See above	P
	The information for the user of protective clothing against infective agents shall contain all the information required by EN 340 and by the relevant standard for that specific type of chemical protective clothing. In addition it shall contain the following information: a) the number of this European Standard; b) the type designation, e.g. type 3-B; c) the biological agents against which the protective clothing has been tested. This information shall be expressed as performance levels, as specified in 4.1.4.1 to 4.1.4.4 for the relevant types of biological challenge; d) all other relevant information on performance levels, preferably as a Table; e) the information necessary for trained persons about: - application and limitations of use (temperature range, etc.); - if relevant, checks to be carried out by the wearer before use; - fitting and adjustments, and any accessories needed to provide the claimed level of protection; - use; - maintenance, cleaning and disinfection;			P

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Form No. : FCLZJ200330158

	- storage; - if relevant, a warning against problems likely to be encountered; - if relevant, illustrations, part numbers and marking of spare parts,etc. - disposal after use.		

Photograph

********** End **********

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Test Result

Personal Protective Equipment - Protective Clothing Against Chemicals -Test Methods and Performance Classification of Chemical Protective Clothing Materials, Seams, Joins and Assemblages
EN 14325:2018

Clause 4.4 Abrasion Resistance

(EN ISO 12947-2:2016;Martindale Abrasion & Pilling Tester, Pressure: 9kPa, Grit 240 abrasion paper.)
(A)

As Received	No. 1	No. 2	No. 3	No. 4	Minimum
The quoted result(Rubs)	>100	>100	>100	>100	>100

Recommended Class: 3
Remark:
1. Visual examination is used for damage assessment after abrasion. If the assessment is performed through visual inspection, the maximum classification that can be claimed is a Class 3.
2. Classification of abrasion resistance: Class 1 >10rubs; Class 2 >40rubs; Class 3 >100rubs; Class 4 >400rubs; Class 5 >1000rubs; Class 6 >2000rubs.

Clause 4.5 Compression-Folding (Schildknecht) Flex Cracking Resistance

(EN ISO 7854:1997, Method B;)
(A)

As Received	No. 1	No. 2	No. 3	Minimum
Warp/Lengthwise(Cycles)	>50000	>50000	>50000	>50000
Weft/Widthwise(Cycles)	>50000	>50000	>50000	>50000

Recommended Class: 6
Remark:
1) Visual examination is used for damage assessment after flex cracking. Visual inspection shall not be used for the performance classification of Type 1 through Type 3(EN 943-1, EN 943-2, EN 14605)
2) Classification of leak tightness after compression-folding(Schildknecht) flex cracking resistance: Class 1 >500cycles; Class 2 >1250cycles; Class 3 >3000cycles; Class 4 >8000cycles; Class 5 >20000cycles; Class 6 >50000cycles.

Clause 4.6 Compression-Folding (Schildknecht) Flex Cracking Resistance at -30℃

(EN ISO 7854:1997, Method B;)
(A)

As Received	No. 1	No. 2	No. 3	Minimum
Warp/Lengthwise(Cycles)	>4000	>4000	>4000	>4000
Weft/Widthwise(Cycles)	>4000	>4000	>4000	>4000

Recommended Class: 6
Remark:
1) Visual examination is used for damage assessment after flex cracking. Visual inspection shall not be used for the performance classification of Type 1 through Type 3(EN 943-1, EN 943-2, EN 14605)
2) Classification of compression-folding(Schildknecht) flex cracking resistance at low temperatures: Class 1 >100cycles; Class 2 >200cycles; Class 3 >500cycles; Class 4 >1000cycles; Class 5 >2000cycles; Class 6 >4000cycles.

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Clause 4.7 Trapezoidal Tear Resistance

(EN ISO 9073-4:1997;)
(A)

As Received	No. 1	No. 2	No. 3	No. 4	No. 5	Minimum
Warp/Length Yarns Torn(N)	36	40	46	45	37	36
Weft/Width Yarns Torn(N)	32	30	34	36	34	30

Recommended Class: 2
Remark:
Classification of trapezoidal tear resistance: Class 1 >10N; Class 2 >20N; Class 3 >40N; Class 4 >60N; Class 5 >100N; Class 6 >150N.

Clause 4.9 Tensile Strength

(EN ISO 13934-1:2013;CRE - 2" Strip)
(A)

As Received	No. 1	No. 2	No. 3	No. 4	No. 5	Minimum
Warp/Length(N)	180	180	170	160	180	160
Weft/Width(N)	170	170	170	170	190	170

Recommended Class: 3
Remark:
Classification of tensile strength: Class 1 >30N; Class 2 >60N; Class 3 >100N; Class 4 >250N; Class 5 >500N; Class 6 >1000N.

Clause 4.10 Puncture Resistance

(EN 863:1995;)
(A)

As Received	No. 1	No. 2	No. 3	No. 4	No. 5	Minimum
Puncture Force(N)	14	13	17	11	13	11

Recommended Class: 2
Remark:
Classification of puncture resistance: Class 1 >5N; Class 2 >10N; Class 3 >50N; Class 4 >100N; Class 5 >150N; Class 6 >250N.

Clause 5.5 Seam Strength
(EN ISO 13935-2:2014)

	# 1	# 2	# 3	Average
Sleeve seam (N)	125(F.R.)	129(F.R.)	132(F.R.)	129(F.R.)
In-side seam (N)	124(F.R.)	140(F.R.)	143(F.R.)	136(F.R.)
Back rise seam (N)	118(F.R.)	93(F.R.)	129(F.R.)	113(F.R.)
Recommended Class	3			

Notes F.R. = Fabric Rupture;
Remark:
Classification of seam strength: Class 1 >30N; Class 2 >50N; Class 3 >75N; Class 4 >125N; Class 5 >300N; Class 6 >500N.

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Protective Clothing for Use against Solid Particulates - Part 1: Performance Requirements for Chemical Protective Clothing Providing Protection to The Full Body Against Airborne Solid Particulates (Type 5 Clothing)
(EN ISO 13982-1:2004+A1:2010)

Clause 4.3 Performance Requirements for Whole Suits-Types 5 (Inward Leakage Test)

Sample A
Clause 4.3.1- General

Requirement	Result	Comment
Type 5 clothing is of the "full-body" type, i.e. it provides protection to at least the trunk, arms and legs, and consists of a one-piece coverall or a two-piece suits. Head protection, e.g. a hood with visor, and/or foot protection may be worn additionally.	Comply	Pass

	Description
Undergarment:	cotton long trousers and a T-shirt with long sleeves
Additional equipment:	/

The physical dimensions of the wearers are shown below

Tested Subjects	Total Height(cm)	Chest girth(cm)	Suit size
Chen	180	120	XXL
Ding	180	110	XXL
Luo	180	92	XXL
Lu	180	106	XXL
Li	180	105	XXL

Prior to testing each suit in accordance with EN ISO 13982-2:2004, a practical test shall be carried out by a human test subject. The test shall comprise three repetitions, at moderate speed, of the "three movement" sequence described in below. If the test subject is not able to perform one or several movements due to the hindrance of the suit or if the movements result in substantial damage to the suit, the suit shall be considered to have failed.

Sequence of movements according to standard

Test sample	Assessment after Movements
1	Pass
2	Pass
3	Pass
4	Pass
5	Pass
6	Pass
7	Pass
8	Pass
9	Pass
10	Pass

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Remark:
-Movement 1: Kneel on both knees, lean forward and place both hands on the floor 45 cm in front of the knees. Crawl forward on hands and knees over a distance of 3 m and crawl backwards again over the same distance.
-Movement 2: Stand with feet shoulder width apart, arms at side. Raise arms until they are parallel to the floor in front of the body. Squat down as far as possible.
-Movement 3: Kneel on right knee, place left foot on floor with left knee bent 90°, left arm hanging loosely at side. Raise left arm fully overhead.

Clause 4.3.2- Inward Leakage of Aerosols of Solid Particles
(EN ISO 13982-2:2004)

The inward leakage value, expressed in percent

Ordination	Value	Ordination	Value	Ordination	Value	Ordination	Value	Ordination	Value	Ordination	Value
1	2.6	16	3.3	31	3.7	46	4.0	61	4.6	76	5.1
2	2.6	17	3.4	32	3.7	47	4.1	62	4.6	77	5.2
3	2.7	18	3.4	33	3.7	48	4.1	63	4.7	78	5.4
4	2.7	19	3.4	34	3.8	49	4.2	64	4.7	79	5.5
5	2.7	20	3.5	35	3.8	50	4.2	65	4.7	80	5.5
6	2.7	21	3.5	36	3.8	51	4.2	66	4.8	81	5.5
7	2.8	22	3.5	37	3.8	52	4.2	67	4.8	82	5.5
8	2.9	23	3.5	38	3.8	53	4.2	68	4.8	83	5.5
9	3.0	24	3.6	39	3.9	54	4.2	69	4.9	84	5.5
10	3.0	25	3.6	40	3.9	55	4.3	70	5.0	85	5.5
11	3.1	26	3.6	41	4.0	56	4.4	71	5.0	86	5.6
12	3.2	27	3.6	42	4.0	57	4.4	72	5.0	87	5.6
13	3.2	28	3.6	43	4.0	58	4.5	73	5.1	88	5.6
14	3.2	29	3.6	44	4.0	59	4.5	74	5.1	89	5.9
15	3.3	30	3.7	45	4.0	60	4.5	75	5.1	90	5.9
The inward leakage value - $L_{jmn,82/90}$					5.5						

The "total inward leakage per suit" value

Ordination	**Value**	**Ordination**	**Value**
1	2.6	6	2.8
2	2.6	7	2.8
3	2.6	8	2.9
4	2.7	9	3.0
5	2.7	10	3.0
The "total inward leakage per suit" value - $L_{S,8/10}$		**2.9**	

Requirement:
When tested accordance with EN ISO 13982-2, the type 5 protective clothing shall be characterized by the following parameters:

- $L_{jmn,82/90}$: the inward leakage value, expressed in percent, corresponding to the 82nd L value of 90, i.e., the inward leakage values measured over all exercises, all sampling positions, all suits and sorted in ascending order;
- $L_{S,8/10}$: the "total inward leakage per suit" value, corresponding to the 8th Ls value of 10, i.e., the Ls values of all suits sorted in ascending order.

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Type 5 chemical protective clothing shall meet at least the following requirements:

- $L_{jmn,82/90}$ ≤30% ;
- $L_{S,8/10}$ ≤15%

Comment: The submitted samples complies with the requirements of EN ISO 13982-1:2004+A1:2010 Clause 4.3 whole Suits Test for Type 5

Sample Photo

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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Management System Certification

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DAkkS

Certificate
No. Q6 090117 0011 Rev. 01

Holder of Certificate: **ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.**
688 XINXING 1ST RD.
314200 PINGHU, JIAXING, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD., 314200 PINGHU, JIAXING, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Syringe, Hypodermic needle, Infusion & transfusion set, Scalp vein set, Irrigation syringe, Oral syringe, Heparin Caps, Three-way Stopcocks (with Extension Tube), Sterile Blood Lancets, Disposable IV Catheter, Sterile Vaginal Dilators for Single Use, Wound Dressings, Urine Bags**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). If applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert Q6 090117 0011 Rev. 01

Report No.: SH2094101
Valid from: 2020-08-31
Valid until: 2021-02-03

Date, 2020-08-31

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstraße 65 · 80339 Munich · Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Certificate
No. Q8 090117 0014 Rev. 00

Holder of Certificate: **ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.**
688 XINXING 1ST RD.
314200 PINGHU, JIAXING, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD., 314200 PINGHU, JIAXING, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **ETO Sterilization Service for Medical Devices**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert Q8 090117 0014 Rev. 00

Report No.: SH2094101

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Head of Certification/Notified Body

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Supplement to Quality System Certificate
No. SUP 090117 0015 Rev. 00

This supplement is only valid in conjunction with the main certificate: **Q8 090117 0014 Rev. 00**

Certificate Holder: **ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.**
688 XINXING 1ST RD.
314200 PINGHU, JIAXING, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD., 314200 PINGHU, JIAXING, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA

The quality system certified as stated in the main certificate additionally fulfils the applicable requirements of

EN ISO 11135:2014 "Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)"

Audit Report: SH2094101
Dated: 2020-01-07

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization

Valid from: 2020-08-31

Christoph Dicks
Head of Certification/Notified Body

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EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 090117 0013 Rev. 01

Manufacturer: ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD.
314200 PINGHU, JIAXING, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Disposable Syringe with Needle,
Hypodermic Needle, Infusion Set,
Blood Transfusion Set,
Burette Infusion Set,
Insulin Syringe, Scalp Vein Set,
Heparin Caps,
Three-Way Stopcocks (with Extension Tube),
Sterile Blood Lancets,
Disposable IV Catheter

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report No.: SH19641EXT01

Valid from: 2020-02-04
Valid until: 2024-05-26

Date, 2019-12-20

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Head of Certification/Notified Body

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EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 090117 0013 Rev. 01

Facility(ies): ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
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EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 090117 0012 Rev. 01

Manufacturer ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
688 XINXING 1ST RD.
314200 PINGHU, JIAXING, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Irrigation Syringe,
Oral Syringe,
Sterile Vaginal Dilators for Single Use,
Wound Dressings,
Urine Bags

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with sterilising and maintaining sterile conditions of the respective device / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH19941EXT01

Valid from: 2020-02-04
Valid until: 2024-05-26

Date, 2019-12-20

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EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 090117 0012 Rev. 01

Facility(ies): ZHEJIANG HUAFU MEDICAL EQUIPMENT CO., LTD.
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