

Technical Data Sheet



Bonete (Capeline) PP Acoperitori Cap, set

+Serix, Mob (Clip) Cap

Producator: XIANTAO ZEFU PROTECTIVE PRODUCTS CO LTD

EU-REP: Sungo Europe B.V.

Technical Data Sheet



Acoperitori Cap (Bonete / Capeline) Unica Folosinta Serix - 100 buc

- Produsul este neabsorbabil, respirabil si nesteril
- Produsul poate fi folosit in spitale, clinici, industria alimentara, de frumuseti etc.
- Capacele confortabile au o deschidere elastica a benzii, care acopera cu usurinta toate stilurile de par
- Deschidere generoasa de 48 cm pentru prinderea in siguranta a parului lung

Caracteristici tehnice:

- Marime: 48 cm
- Culoare: albastru
- Material: Polipropilena (PP)
- Ambalare - 100 buc/set

Produsul este avizat pentru uz in:

- Medicina (avizat ANMDMR)
- Laboratoare
- HoReCa
- Industrie Alimentara
- Beauty
- Curatenie

Detalii suplimentare:

- [Aviz ANMDMR](#)

Technical Data Sheet

Product Name	Mob (Clip) Cap					
Manufacture	Xiantao Zefu Protective Productive Co.,Ltd.					
Ref: 180322	CE ISO13485 FDA approved manufacturer					
Specification:						
Material				Non Woven Polypropylene		
Thickness				0.02mm		
Size:				19"	inch	Allowance
Length (A)				48cm	+ /- 1cm	
Packing:						
100pcs / bag						
2000pcs / carton						
Remark:	With elastic, machine made					
Colour:	Blue					
Application:	Hospital/ Laboratory/ Farming/ Food/ Cleanning					

Fisa tehnica produs

Nume produs:		Boneta (acoperitor) cap	
Producator		Xiantao Zefu Protective Productive Co.,Ltd.	
Ref: 180322		Producator aprobat de FDA, CE ISO13485	
Specificatii:			
Material	Polipropilena netesuta		
Grosime	0.02mm		
Marime:	19"	inch	Abatere
Lungime (A)		48cm	+/- 1cm
Ambalare:			
100buc/ punga			
2000buc/ cutie			
Remarca: cu elastic, realizat la masina			
Culoare: Albastru			
Aplicatii: Spital/ Laboratoare/ Agricultura/ Alimentatie/ Curatenie			





DECLARATIE DE CONFORMITATE

CONFORM CU (EU) 2017/45 PRIVIND DISPOZITIVELE MEDICALE

Reprezentant european

SUNGO Europe B.V.

Bdl. Fascinatio 522, Unit 1.7, 2909VA

Capelle aan den IJssel, Tarile de jos SRN:

NL-AR-000000247

Evaluarea conformitatii

Procedura de evaluare a conformitatii

Anexele: II+III la Regulamentul (EU)

2017/745

Standarde aplicate

EN ISO 14971: 2019

EN ISO 15223-1: 2021

EN ISO 20417:2021

EN ISO 10993-1 : 2020

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

Remarca

*Declaratia de conformitate este valabila in
concordanta cu documentul tehnic eliberat CE/
MDR-T0207-03.*

*Toata documentatia justificata se pastreaza la sediul
producatorului.*

*Declaratia de conformitate este exclusiv
responsabilitatea producatorului.*

Producator

**Nume: XIANTAO ZEFU PROTECTIVE PRODUCTS
CO.,LTD**

**Adresa: 3#, 1ST CHUANGYE ROAD, ZHONGLING
INDUSTRY PARK, PENGCHANG TOWN, Oras
XIANTAO**

SRN: CN-MF-000009788

Informatii produs

Nume : Acoperitor cap

Model : ZFJ:P001, ZFJ:P002, ZFJ:P003

EMDN: T0207

GMDN: 32297

**Basic UDI-DI : 697544201ZFMCP001 BW,
697544201ZFMCP0028Y, 697544201 ZFMCP00392**

CLASIFICARE: Clasa I in cord cu Regula 1, Anexa
VIII, Regulament (EU) 2017/745

Declaratie

Prin prezenta, declaram ca produsele mentionate mai
sus inepinesc cerintele Regulamentului (EU)
2017/745 privind dispozitivele medicale si standrdele
aplicate mai sus.

Signature: Tony Xia

Date: 19/06/2021

Pozitie

General Manager

* Place: Hubei/China





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.

Fascinato Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands

SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE/MDR-T0207-03.*

*All the supporting documentation is retained at the
premises of the manufacturer.*

*The Declaration of Conformity is exclusively under
the sole responsibility of the manufacturer.*

Manufacturer

Name: XIANTAO ZEFU PROTECTIVE PRODUCTS
CO.,LTD

Address: 3#, 1ST CHUANGYE ROAD, ZHONGLING
INDUSTRY PARK, PENGCHANG TOWN, XIANTAO
CITY

SRN: CN-MF-000009788

Product Information

Name : Mob Cap (Head Cover)

Model :

ZFMCPW01, ZFMCPW02, ZFMCPW03, ZFMCPW04
ZFMCPB01, ZFMCPB02, ZFMCPB03, ZFMCPB04
ZFMCPBK01, ZFMCPBK02, ZFMCPBK03, ZFMCPBK04
ZFMCPG01, ZFMCPG02, ZFMCPG03, ZFMCPG04
ZFMCP01, ZFMCP02, ZFMCP03, ZFMCP04

EMDN : T0207

GMDN: 32297

Basic UDI-DI : 697544201ZFMCP0018W,
697544201ZFMCP0028Y, 697544201ZFMCP00392

Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned
products meet the requirements of Medical Device
Regulation (EU) 2017/745 and the applicable
standards above.

Signature: Tony Xia

Position: General Manager

Date: 19/06/2021

Place: Hubei/China





CIBG
Ministry of Health,
Welfare and Sport

> Return address: PO Box 16114, 2500 BC, The Hague

SUNGO Europe B.V.
Attn: Mr R. Luo
Fascinatio Boulevard 522 (Unit 1.7)
2909VA Capelle aan den IJssel

Date: 13 June 2022

Subject: Notification of Class I medical device

Farmatec

Address: Hoftoren
Rijnstraat 50
2515 XP, The Hague

T 070 340 6161

<http://hulpmiddelen.farmatec.nl>

Information via:
medische_hulpmiddelen@minvws.nl

Our reference:
CIBG-20223489

Attachments
-

Your request
12 May 2022

*Correspondence should only be
addressed to the return address, stating
the date and reference of this letter.*

Dear Mr. Luo,

I hereby acknowledge the receipt of the notification on 12 May 2022 of the Class I medical device, that the company XIANTAO ZEFU PROTECTIVE PRODUCTS CO., LTD, with their European authorized representative SUNGO Europe B.V., as manufacturer, in accordance with Regulation (EU) 2017/745 (Medical Devices Regulation, MDR), wishes to bring to the market.

The product is registered under the following reference. I request that you state the corresponding reference in all further correspondence about this product and keep it on hand during telephone conversations.

Isolation Gown
(geen merknaam) (NL-CA002-2022-70443)

Lab Coat
(geen merknaam) (NL-CA002-2022-70445)

Mob Cap
(geen merknaam) (NL-CA002-2022-70444)

Shoe Cover
(geen merknaam) (NL-CA002-2022-70446)

Sleeve Cover
(geen merknaam) (NL-CA002-2022-70447)

I would like to point out that, according to the MDR, medical devices placed on the market must have a device indication system (Unique Device Indication,UDI)¹, and manufacturers, authorized representatives and importers should be registered in the

10.g.vart.29 MDR
20.g.vart.31 MDR

European Databank on Medical Devices (EUDAMED)². Annex VI of the MDR contains the information to be provided during registration.

At the moment EUDAMED is not yet in use, therefore with regard to the above-mentioned subject, it is sufficient that you have notified your product in accordance with current laws and regulations.

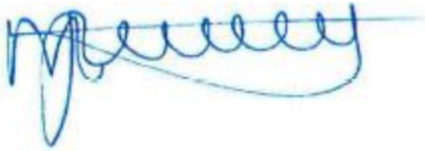
Once EUDAMED is fully operational, the manufacturer or its authorized representative is expected to register the above-mentioned device in EUDAMED within eighteen months.³

I would also like to point out, for the record, that the registration of your communication regarding the delivery of the above-mentioned product is only an administrative act. This confirmation of receipt therefore does not constitute a decision regarding the qualification of the product concerned as a medical device within the meaning of Art. 1 of the Medical Devices Act (WMH), nor concerning the classification of the device in risk class I.

The Minister for Medical Care and Sport,
on behalf of,

Department head

Farmatec



Dr. M.J. van de Velde

² According to Art. 31 MDR.

³ www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf. See Question and Answer number 20.



CIBG
Ministerul
Sanatatii,
Bunastarii Sociale
si Sportului

> Adresa Returnare: PO Box 16114, 2500 BC, Haga

SUNGO Europe B.V.
Attn: Mr R. Luo
Fascinatio Boulevard 522 (Unit 1.7)
2909VA Capelle aan den IJssel

Data: 13 Iunie 2022

Subiect: Notificarea dispozitivului medical din Clasa I

Farmatec

Adresa: Hoftoren
Rijnstraat 50
2515 XP, Haga

T 070 340 6161

<http://hulpmiddelen.farmatec.nl>

Informatii via:

medische_hulpmiddelen@minvws.nl

Referinta:

CIBG-20223489

Atasamente:

-

Referinta noastra:

12 Mai 2022

*Corespondenta trebuie adresata numai la
adresa de retur, mentionand data si referinta
acestei scrisori*

Stimate Domnule Luo,

Prin prezenta, confirm primirea notificarii din 12 Mai 2022 a dispozitivului medical din clasa I, pe care compania XIANTAO ZEFU PROTECTIVE PRODUCTS CO., LTD, cu reprezentantul sau european autorizat SUNGO Europe B.V, in calitate de producator, in acord cu Regulamentul (EU) 2017/745 (Regulamentul privind dispozitivele medicale, MDR), doreste sa il introduca pe piata.

Produsul este inregistrat sub urmatoarea referinta. Va rog sa mentionati referinta corespunzatoare in toata corespondenta ulterioara referitoare la acest produs si sa o pastrati la indemana in timpul converatiilor viitoare..

Halat chirurgical

(referinta) (NL-CA002-2022-70443)

Haina laborator

(referinta) (NL-CA002-2022-70445)

Acoperitori cap

(referinta) (NL-CA002-2022-70444)

Acoperitori pantofi

(referinta) (NL-CA002-2022-70446)

Mansete

(referinta) (NL-CA002-2022-70447)

As dori sa subliniez ca, in conformitate cu MDR, dispozitivele medicale introduse pe piata trebuie sa aiba un sistem de indicare a dispozitivului Indicatie Unica a Dispozitivului (UDI)¹, iar producatorii, reprezentanti autorizati si importatori trebuie sa fie inregistrati in

¹10.g.v.art.29 MDR
20.g.v.art.31 MDR

Banca Europeana de Date privind Dispozitivele Medicale (EUDAMED)². Anexa VI la MRD contine informatiile care trebuie furnizate in timpul inregistrarii.

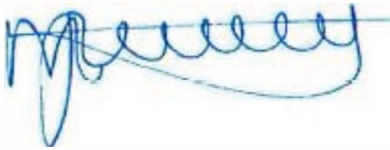
In prezent, EUDAMED nu este inca in uz, prin urmare, in ceea ce priveste subiectul mentionat mai sus, este suficient sa fie notificat produsul in conformitate cu legile si reglementarile in vigoare.

Odata ce EUDAMED este pe deplin operational, producatorul sau reprezentantul autorizat se asteapta sa inregistreze dispozitivul mentionat mai sus in EUDAMED in termen de optsprezece luni. De asemenea, as dori sa subliniez, spre evidenta, ca inregistrarea comenzii dumneavoastra privind livrarea produsului mentionat mai sus este doar un act administrativ. Prin urmare, aceasta confirmare de primire nu contituie o decizie privind calificarea produsului in cauza drept dispozitiv medical in sensul art 1 din Legea privind dispozitivele medicale (WM1-1), nici privind clasificarea dispozitivului in clasa de risc I.

Ministerul Asistentei Medicale si Sportului,
in numele,

Sef departament

Farmatec



Dr. M.J. van de Velde

² In acord cu Art. 31 MDR.

³ www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf. See Question and Answer number 20.

Test Report (SVHC)

No. CKGEC2200942301

Date: 09 Nov 2022

Page 1 of 22

Client Name : XIANTAO ZEFU PROTECTIVE PRODUCTS CO.,LTD

Client Address : 3#,1ST CHUANGYE ROAD,ZHONGLING INDUSTRY PARK,PENGCHANG TOWN,XIANTAO CITY

Sample Name : POLYPROPYLENE(PP)MATERIAL

The above sample(s) and information were provided by the client.

SGS Job No. : 10021119 - CQ

Date of Sample Received : 03 Nov 2022

Testing Period : 03 Nov 2022 - 09 Nov 2022

Test Requested : As requested by client, SVHC screening is performed according to:

- (i) Two hundred and twenty-four (224) substances in the Candidate List of Substances of Very High Concern (SVHC) for authorization published by European Chemicals Agency (ECHA) on and before Jun 10, 2022 regarding Regulation (EC) No 1907/2006 concerning the REACH.
- (ii) Nine (9) substances in the Public Consultation List of potential Substances of Very High Concern (SVHC) published by European Chemicals Agency (ECHA) on and before Sep 2, 2022 regarding Regulation (EC) No 1907/2006 concerning the REACH.
- (iii) One (1) potential Substances of Very High Concern (SVHC) in the notification of WTO on Jun 1, 2021.

Test Result(s) : Please refer to next page(s).

Summary :

According to the specified scope and evaluation screening, the test results of SVHC are $\leq 0.1\%$ (w/w) in the submitted sample.	PASS
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Signed for and on behalf of
SGS-CSTC Standards Technical Services (Chongqing) Co., Ltd.

Mary Zou

Mary Zou

Approved Signatory

scan to see the report



2AB3DE16



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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

SGS-CSTC Standards Technical Services (Chongqing) Co., Ltd.
Chemical Laboratory

Liangjing Industrial Park, No.37, Cuitao Road, Yubei District, Chongqing, China 401120
中国·重庆·渝北区翠桃路37号(凉井工业园) 邮编: 401120

t (86-23) 6311 0882 www.sgsgroup.com.cn
t (86-23) 6311 0882 sgs.china@sgs.com

Member of the SGS Group (SGS SA)

Test Report (SVHC)

No. CKGEC2200942301

Date: 09 Nov 2022

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Remark :

1. The chemical analysis of specified SVHC is performed by means of currently available analytical techniques against the following SVHC related documents published by ECHA:
<http://echa.europa.eu/web/guest/candidate-list-table>

These lists are under evaluation by ECHA and may subject to change in the future.

2. REACH obligation:

2.1 Concerning article(s):

Communication:

Article 33 of Regulation (EC) No 1907/2006 requires supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance in the Candidate List.

Notification:

In accordance with Regulation (EC) No 1907/2006, any EU producer or importer of articles shall notify ECHA, in accordance with paragraph 4 of Article 7, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1) of the Regulation, if (a) the substance in the Candidate List is present in those articles in quantities totaling over one tonne per producer or importer per year; and (b) the substance in the Candidate List is present in those articles above a concentration of 0.1% weight by weight (w/w).

SGS adopts the ruling of the Court of Justice of the European Union on the definition of an article under REACH unless indicated otherwise. Detail explanation is available at the following link:

<http://www.sgs.com/-/media/global/documents/technical-documents/technical-bulletins/sgs-crs-position-statement-on-svhc-in-articles-a4-en-16-06.pdf?la=en>

2.2 Concerning material(s):

Test results in this report are based on the tested sample. This report refers to testing result of tested sample submitted as homogenous material(s). In case such material is being used to compose an article, the results indicated in this report may not represent SVHC concentration in such article. If this report refers to testing result of composite material group by equal weight proportion, the material in each composite test group may come from more than one article.

If the sample is a substance or mixture, and it directly exports to EU, client has the obligation to comply with the supply chain communication obligation under Article 31 of Regulation (EC) No. 1907/2006 and the conditions of Authorization of substance of very high concern included in the Annex XIV of the Regulation (EC) No. 1907/2006.

2.3 Concerning substance and preparation:

If a SVHC is found over 0.1% (w/w) and/or the specific concentration limit which is set in Regulation (EC) No 1272/2008 and its amendments, client is suggested to prepare a Safety

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Member of the SGS Group (SGS SA)



Test Report
(SVHC)

No. CKGEC2200942301

Date: 09 Nov 2022

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Data Sheet (SDS) against the SVHC to comply with the supply chain communication obligation under Regulation (EC) No 1907/2006, in which:

- a substance that is classified as hazardous under the CLP Regulation (EC) No 1272/2008.
- a mixture that is classified as hazardous under the CLP Regulation (EC) No 1272/2008, when it contains a substance with concentration equal to, or greater than the classification limit as set in Regulation (EC) No. 1272/2008; or
- a mixture is not classified as hazardous under the CLP Regulation (EC) No 1272/2008, but contains either:
 - (a) a substance posing human health or environmental hazards in an individual concentration of $\geq 1\%$ by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures) or $\geq 0.2\%$ by volume for gaseous mixtures; or
 - (b) a substance that is PBT, or vPvB in an individual concentration of $\geq 0.1\%$ by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures); or
 - (c) a substance on the SVHC candidate list (for reasons other than those listed above), in an individual concentration of $\geq 0.1\%$ by weight for non-gaseous mixtures; or
 - (d) a substance for which there are Europe-wide workplace exposure limits.

3. If a SVHC is found over the reporting limit, client is suggested to identify the component which contains the SVHC and the exact concentration of the SVHC by requesting further quantitative analysis from the laboratory.

Test Sample :

Sample Description :

Specimen No.	SGS Sample ID	Description	Number of SVHC Tested
SN1	CKG22-009423.001	White translucent material	234

Test Method :

SGS In-House method- CQTC-CCL-TOP-019-01, CQTC-CCL-TOP-019-02, Analyzed by ICP-OES, UV-VIS, GC-MS, HPLC-DAD/MS and Colorimetric Method.



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SGS-CSTC (Shanghai) Technical Services (Chongqing) Co., Ltd.
Chemical Laboratory

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Test Report (SVHC)

No. CKGEC2200942301

Date: 09 Nov 2022

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Test Result: (Substances in the Candidate List of SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All tested SVHC in candidate list	-	ND	-

Test Result: (Potential SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All tested Potential SVHC	-	ND	-

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Test Report (SVHC)

No. CKGEC2200942301

Date: 09 Nov 2022

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Notes :

1. The table above only shows detected SVHC, and SVHC that below RL are not reported. Please refer to Appendix for the full list of tested SVHC.
 2. RL = Reporting Limit (Test data will be shown if it $\geq$ RL. RL is not regulatory limit.) ND = Not detected (lower than RL),
ND is denoted on the SVHC substance.
 3. * The test result is based on the calculation of selected element(s) and to the worst-case scenario.
** The test result is based on the calculation of selected marker(s) and to the worst-case scenario.
 4. RL = 0.005% is evaluated for element (i.e. cobalt, arsenic, lead, chromium (VI), aluminum, zirconium, boron, strontium, zinc, antimony, titanium, barium, cadmium respectively), except molybdenum
RL=0.0005%, boron RL=0.0025% (only for Lead bis(tetrafluoroborate)), fluorine RL=0.050%.
 5. Calculated concentration of boric compounds are based on water extractive boron detected by ICP-OES.
Calculated concentration of Barium diboron tetraoxide is based on water extractive boron and barium detected by ICP-OES.
 6. § The substance is proposed for the identification as SVHC only where it contains Michler's ketone (CAS Number: 90-94-8) or Michler's base (CAS Number: 101-61-1) $\geq 0.1\%$ (w/w).
 7. / = Potential SVHC
- Unless otherwise stated, the decision rule for conformity reporting is based on Binary Statement for Simple Acceptance Rule ($w=0$) stated in ILAC-G8:09/2019.



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Batch	No.	Substance Name	CAS No.	RL (%)	Sample ID
I	1	4,4' -Diaminodiphenylmethane(MDA)	101-77-9	0.050	001
I	2	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	0.050	001
I	3	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	0.050	001
I	4	Anthracene	120-12-7	0.050	001
I	5	Benzyl butyl phthalate (BBP)	85-68-7	0.050	001
I	6	Bis (2-ethylhexyl)phthalate (DEHP)	117-81-7	0.050	001
I	7	Bis(tributyltin)oxide (TBTO)	56-35-9	0.050	001
I	8	Cobalt dichloride*	7646-79-9	0.005	001
I	9	Diarsenic pentaoxide*	1303-28-2	0.005	001
I	10	Diarsenic trioxide*	1327-53-3	0.005	001
I	11	Dibutyl phthalate (DBP)	84-74-2	0.050	001
I	12	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified (α -HBCDD, β -HBCDD, γ -HBCDD)	-	0.050	001
I	13	Lead hydrogen arsenate*	7784-40-9	0.005	001
I	14	Sodium dichromate*	7789-12-0, 10588-01-9	0.005	001
I	15	Triethyl arsenate*	15606-95-8	0.005	001
II	16	2,4-Dinitrotoluene	121-14-2	0.050	001
II	17	Acrylamide	79-06-1	0.050	001
II	18	Anthracene oil**	90640-80-5	0.050	001
II	19	Anthracene oil, anthracene paste**	90640-81-6	0.050	001



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Batch	No.	Substance Name	CAS No.	RL (%)	Sample ID
II	20	Anthracene oil, anthracene paste, anthracene fraction**	91995-15-2	0.050	001
II	21	Anthracene oil, anthracene paste, distn. lights**	91995-17-4	0.050	001
II	22	Anthracene oil, anthracene-low**	90640-82-7	0.050	001
II	23	Diisobutyl phthalate(DIBP)	84-69-5	0.050	001
II	24	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)*	12656-85-8	0.005	001
II	25	Lead chromate*	7758-97-6	0.005	001
II	26	Lead sulfochromate yellow (C.I. Pigment Yellow 34)*	1344-37-2	0.005	001
II	27	Pitch, coal tar, high temp.**	65996-93-2	0.050	001
II	28	Tris(2-chloroethyl)phosphate	115-96-8	0.050	001
III	29	Ammonium dichromate*	7789-09-5	0.005	001
III	30	Boric acid*	-	0.005	001
III	31	Disodium tetraborate, anhydrous*	1303-96-4, 1330-43-4, 12179-04-3	0.005	001
III	32	Potassium chromate*	7789-00-6	0.005	001
III	33	Potassium dichromate*	7778-50-9	0.005	001
III	34	Sodium chromate*	7775-11-3	0.005	001
III	35	Tetraboron disodium heptaoxide, hydrate*	12267-73-1	0.005	001
III	36	Trichloroethylene	79-01-6	0.050	001
IV	37	2-Ethoxyethanol	110-80-5	0.050	001
IV	38	2-Methoxyethanol	109-86-4	0.050	001



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Batch	No.	Substance Name	CAS No.	RL (%)	Sample ID
IV	39	Chromic acid, Oligomers of chromic acid and dichromic acid, Dichromic acid*	-	0.005	001
IV	40	Chromium trioxide*	1333-82-0	0.005	001
IV	41	Cobalt(II) carbonate*	513-79-1	0.005	001
IV	42	Cobalt(II) diacetate*	71-48-7	0.005	001
IV	43	Cobalt(II) dinitrate*	10141-05-6	0.005	001
IV	44	Cobalt(II) sulphate*	10124-43-3	0.005	001
V	45	1,2,3-trichloropropane	96-18-4	0.050	001
V	46	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	0.050	001
V	47	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4	0.050	001
V	48	1-methyl-2-pyrrolidone	872-50-4	0.050	001
V	49	2-ethoxyethyl acetate	111-15-9	0.050	001
V	50	Hydrazine	7803-57-8, 302-01-2	0.050	001
V	51	Strontium chromate*	7789-06-2	0.005	001
VI	52	1,2-Dichloroethane	107-06-2	0.050	001
VI	53	2,2'-dichloro-4,4'-methylenedianiline	101-14-4	0.050	001
VI	54	2-Methoxyaniline; o-Anisidine	90-04-0	0.050	001
VI	55	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	0.050	001
VI	56	Aluminosilicate Refractory Ceramic Fibres *	-	0.005	001



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Batch	No.	Substance Name	CAS No.	RL (%)	Sample ID
VI	57	Arsenic acid*	7778-39-4	0.005	001
VI	58	Bis(2-methoxyethyl) ether	111-96-6	0.050	001
VI	59	Bis(2-methoxyethyl) phthalate	117-82-8	0.050	001
VI	60	Calcium arsenate*	7778-44-1	0.005	001
VI	61	Dichromium tris(chromate) *	24613-89-6	0.005	001
VI	62	Formaldehyde, oligomeric reaction products with aniline	25214-70-4	0.050	001
VI	63	Lead diazide, Lead azide*	13424-46-9	0.005	001
VI	64	Lead dipicrate*	6477-64-1	0.005	001
VI	65	Lead styphnate*	15245-44-0	0.005	001
VI	66	N,N-dimethylacetamide	127-19-5	0.050	001
VI	67	Pentazinc chromate octahydroxide*	49663-84-5	0.005	001
VI	68	Phenolphthalein	77-09-8	0.050	001
VI	69	Potassium hydroxyoctaoxodizincatedichromate*	11103-86-9	0.005	001
VI	70	Trilead diarsenate*	3687-31-8	0.005	001
VI	71	Zirconia Aluminosilicate Refractory Ceramic Fibres*	-	0.005	001
VII	72	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Blue 26)§	2580-56-5	0.050	001
VII	73	[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)§	548-62-9	0.050	001



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Batch	No.	Substance Name	CAS No.	RL (%)	Sample ID
VII	74	1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	112-49-2	0.050	001
VII	75	1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	110-71-4	0.050	001
VII	76	4,4'-bis(dimethylamino) benzophenone (Michler's Ketone)	90-94-8	0.050	001
VII	77	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol§	561-41-1	0.050	001
VII	78	Diboron trioxide*	1303-86-2	0.005	001
VII	79	Formamide	75-12-7	0.050	001
VII	80	Lead(II) bis(methanesulfonate)*	17570-76-2	0.005	001
VII	81	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	101-61-1	0.050	001
VII	82	TGIC (1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione)	2451-62-9	0.050	001
VII	83	α,α-Bis[4-(dimethylamino)phenyl]-4-(phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) §	6786-83-0	0.050	001
VII	84	β-TGIC (1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)	59653-74-6	0.050	001
VIII	85	[Phthalato(2-)]dioxotrilead*	69011-06-9	0.005	001
VIII	86	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	0.050	001
VIII	87	1,2-Diethoxyethane	629-14-1	0.050	001
VIII	88	1-Bromopropane	106-94-5	0.050	001
VIII	89	3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	0.050	001
VIII	90	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	-	0.050	001



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Batch	No.	Substance Name	CAS No.	RL (%)	Sample ID
VIII	91	4,4'-Methylenedi-o-toluidine	838-88-0	0.050	001
VIII	92	4,4'-Oxydianiline and its salts	101-80-4	0.050	001
VIII	93	4-Aminoazobenzene	60-09-3	0.050	001
VIII	94	4-Methyl-m-phenylenediamine	95-80-7	0.050	001
VIII	95	4-Nonylphenol, branched and linear	-	0.050	001
VIII	96	6-Methoxy-m-toluidine	120-71-8	0.050	001
VIII	97	Acetic acid, lead salt, basic*	51404-69-4	0.005	001
VIII	98	Biphenyl-4-ylamine	92-67-1	0.050	001
VIII	99	Bis(pentabromophenyl) ether (DecaBDE)	1163-19-5	0.050	001
VIII	100	Cyclohexane-1,2-dicarboxylic anhydride, cis-cyclohexane-1,2-dicarboxylic anhydride, trans-cyclohexane-1,2-dicarboxylic anhydride	-	0.050	001
VIII	101	Diazeno-1,2-dicarboxamide (C,C'-azodi(formamide))	123-77-3	0.050	001
VIII	102	Dibutyltin dichloride (DBTC)	683-18-1	0.050	001
VIII	103	Diethyl sulphate	64-67-5	0.050	001
VIII	104	Diisopentylphthalate	605-50-5	0.050	001
VIII	105	Dimethyl sulphate	77-78-1	0.050	001
VIII	106	Dinoseb	88-85-7	0.050	001
VIII	107	Dioxobis(stearato)trilead*	12578-12-0	0.005	001
VIII	108	Fatty acids, C16-18, lead salts*	91031-62-8	0.005	001



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VIII	109	Furan	110-00-9	0.050	001
VIII	110	Henicosafuoroundecanoic acid	2058-94-8	0.050	001
VIII	111	Heptacosafuorotetradecanoic acid	376-06-7	0.050	001
VIII	112	Hexahydromethylphthalic anhydride, Hexahydro-4-methylphthalic anhydride, Hexahydro-1-methylphthalic anhydride, Hexahydro-3-methylphthalic anhydride	-	0.050	001
VIII	113	Lead bis(tetrafluoroborate)*	13814-96-5	0.005	001
VIII	114	Lead cyanamidate*	20837-86-9	0.005	001
VIII	115	Lead dinitrate*	10099-74-8	0.005	001
VIII	116	Lead monoxide*	1317-36-8	0.005	001
VIII	117	Lead oxide sulfate*	12036-76-9	0.005	001
VIII	118	Lead tetroxide (orange lead)*	1314-41-6	0.005	001
VIII	119	Lead titanium trioxide*	12060-00-3	0.005	001
VIII	120	Lead titanium zirconium oxide*	12626-81-2	0.005	001
VIII	121	Methoxyacetic acid	625-45-6	0.050	001
VIII	122	Methyloxirane (Propylene oxide)	75-56-9	0.050	001
VIII	123	N,N-dimethylformamide	68-12-2	0.050	001
VIII	124	N-Methylacetamide	79-16-3	0.050	001
VIII	125	N-Pentyl-isopentylphthalate	776297-69-9	0.050	001
VIII	126	o-Aminoazotoluene	97-56-3	0.050	001
VIII	127	o-Toluidine	95-53-4	0.050	001



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Appendix

Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)	Sample ID
VIII	128	Pentacosafuorotridecanoic acid	72629-94-8	0.050	001
VIII	129	Pentalead tetraoxide sulphate*	12065-90-6	0.005	001
VIII	130	Pyrochlore, antimony lead yellow*	8012-00-8	0.005	001
VIII	131	Silicic acid, barium salt, lead-doped*	68784-75-8	0.005	001
VIII	132	Silicic acid, lead salt*	11120-22-2	0.005	001
VIII	133	Sulfurous acid, lead salt, dibasic*	62229-08-7	0.005	001
VIII	134	Tetraethyllead*	78-00-2	0.005	001
VIII	135	Tetralead trioxide sulphate*	12202-17-4	0.005	001
VIII	136	Tricosafuorododecanoic acid	307-55-1	0.050	001
VIII	137	Trilead bis(carbonate)dihydroxide (basic lead carbonate)*	1319-46-6	0.005	001
VIII	138	Trilead dioxide phosphonate*	12141-20-7	0.005	001
IX	139	4-Nonylphenol, branched and linear, ethoxylated	-	0.050	001
IX	140	Ammonium pentadecafluorooctanoate (APFO)**	3825-26-1	0.050	001
IX	141	Cadmium oxide*	1306-19-0	0.005	001
IX	142	Cadmium	7440-43-9	0.005	001
IX	143	Dipentyl phthalate (DPP)	131-18-0	0.050	001
IX	144	Pentadecafluorooctanoic acid (PFOA)	335-67-1	0.050	001
X	145	Cadmium sulphide*	1306-23-6	0.005	001
X	146	Dihexyl phthalate	84-75-3	0.050	001



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X	147	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	0.050	001
X	148	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	0.050	001
X	149	Imidazolidine-2-thione; (2-imidazoline-2-thiol)	96-45-7	0.050	001
X	150	Lead di(acetate)*	301-04-2	0.005	001
X	151	Trixylyl phosphate	25155-23-1	0.050	001
XI	152	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	0.050	001
XI	153	Cadmium chloride*	10108-64-2	0.005	001
XI	154	Sodium perborate; perboric acid, sodium salt*	-	0.005	001
XI	155	Sodium peroxometaborate*	7632-4-4	0.005	001
XII	156	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	0.050	001
XII	157	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	0.050	001
XII	158	2-ethylhexyl 10-ethyl-4,4-diethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	0.050	001
XII	159	Cadmium fluoride*	7790-79-6	0.005	001
XII	160	Cadmium sulphate*	10124-36-4,311 19-53-6	0.005	001



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Batch	No.	Substance Name	CAS No.	RL (%)	Sample ID
XII	161	Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate & 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE&MOTE)	-	0.050	001
XIII	162	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate	-	0.050	001
XIII	163	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual isomers of [1] and [2] or any combination thereof]		0.050	001
XIV	164	1,3-propanesultone	1120-71-4	0.050	001
XIV	165	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl) phenol (UV-327)	3864-99-1	0.050	001
XIV	166	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl) phenol (UV-350)	36437-37-3	0.050	001
XIV	167	Nitrobenzene	98-95-3	0.050	001
XIV	168	Perfluorononan-1-oic-acid and its sodium and ammonium salts	-	0.050	001
XV	169	Benzo[def]chrysene (Benzo[a]pyrene)	50-32-8	0.050	001
XVI	170	4,4'-isopropylidenediphenol (bisphenol A)	80-05-7	0.050	001
XVI	171	4-Heptylphenol, branched and linear	-	0.050	001
XVI	172	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	-	0.050	001



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Batch	No.	Substance Name	CAS No.	RL (%)	Sample ID
XVI	173	p-(1,1-dimethylpropyl)phenol	80-46-6	0.050	001
XVII	174	Perfluorohexane-1-sulphonic acid and its salts		0.050	001
XVIII	175	Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™) [covering any of its individual anti- and syn-isomers or any combination thereof]	/	0.050	001
XVIII	176	Benz[a]anthracene	56-55-3	0.050	001
XVIII	177	Cadmium nitrate*	10325-94-7	0.005	001
XVIII	178	Cadmium carbonate*	513-78-0	0.005	001
XVIII	179	Cadmium hydroxide*	21041-95-2	0.005	001
XVIII	180	Chrysene	218-01-9	0.050	001
XVIII	181	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear]	/	0.050	001
XIX	182	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride)	552-30-7	0.050	001
XIX	183	Benzo[ghi]perylene	191-24-2	0.050	001
XIX	184	Decamethylcyclopentasiloxane (D5)	541-02-6	0.050	001
XIX	185	Dicyclohexyl phthalate (DCHP)	84-61-7	0.050	001
XIX	186	Disodium octaborate*	12008-41-2	0.005	001
XIX	187	Dodecamethylcyclohexasiloxane (D6)	540-97-6	0.050	001
XIX	188	Ethylenediamine	107-15-3	0.050	001



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Batch	No.	Substance Name	CAS No.	RL (%)	Sample ID
XIX	189	Lead	7439-92-1	0.005	001
XIX	190	Octamethylcyclotetrasiloxane (D4)	556-67-2	0.050	001
XIX	191	Terphenyl hydrogenated	61788-32-7	0.050	001
XX	192	1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor)	15087-24-8	0.050	001
XX	193	2,2-bis(4'-hydroxyphenyl)-4-methylpentane	6807-17-6	0.050	001
XX	194	Benzo[k]fluoranthene	207-08-9	0.050	001
XX	195	Fluoranthene	206-44-0	0.050	001
XX	196	Phenanthrene	85-01-8	0.050	001
XX	197	Pyrene	129-00-0	0.050	001
XXI	198	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)	-	0.050	001
XXI	199	2-methoxyethyl acetate	110-49-6	0.050	001
XXI	200	4-tert-butylphenol	98-54-4	0.050	001
XXI	201	Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear (4-NP)	-	0.050	001
XXII	202	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	0.050	001
XXII	203	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	0.050	001
XXII	204	Diisohexyl phthalate	71850-09-4	0.050	001



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Batch	No.	Substance Name	CAS No.	RL (%)	Sample ID
XXII	205	Perfluorobutane sulfonic acid (PFBS) and its salts	-	0.050	001
XXIII	206	1-vinylimidazole	1072-63-5	0.050	001
XXIII	207	2-methylimidazole	693-98-1	0.050	001
XXIII	208	Butyl 4-hydroxybenzoate	94-26-8	0.050	001
XXIII	209	Dibutylbis(pentane-2,4-dionato-O,O')tin**	22673-19-4	0.050	001
XXIV	210	bis(2-(2-methoxyethoxy)ethyl) ether	143-24-8	0.050	001
XXIV	211	Diocetyl tin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety**	-	0.050	001
XXV	212	1,4-dioxane	123-91-1	0.050	001
XXV	213	2,2-bis(bromomethyl)propane 1,3-diol (BMP) 2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA) 2,3-dibromo-1-propanol (2,3-DBPA)	3296-90-0 36483-57-5 1522-92-5 96-13-9	0.050	001
XXV	214	2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers	-	0.050	001
XXV	215	4,4'-(1-methylpropylidene)bisphenol (bisphenol B)	77-40-7	0.050	001
XXV	216	Glutaral	111-30-8	0.050	001
XXV	217	Medium-chain chlorinated paraffins (MCCP) [UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C14 to C17]	-	0.050	001
XXV	218	Orthoboric acid, sodium salt*	13840-56-7	0.005	001



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XXV	219	Phenol, alkylation products (mainly in para position) with C12-rich branched or linear alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP)	-	0.050	001
XXVI	220	(±)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one covering any of the individual isomers and/or combinations thereof (4-MBC)	-	0.050	001
XXVI	221	6,6'-di-tert-butyl-2,2'-methylenedi-p-creso I (DBMC)	119-47-1	0.050	001
XXVI	222	S-(tricyclo[5.2.1.0'2,6]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate	255881-94-8	0.050	001
XXVI	223	Tris(2-methoxyethoxy)vinylsilane	1067-53-4	0.050	001
XXVII	224	N-(hydroxymethyl)acrylamide	924-42-5	0.050	001
/	225	1,1'-[ethane-1,2-diylbis(oxy)]bis[2,4,6-tribromobenzene]	37853-59-1	0.050	001
/	226	2,2',6,6'-tetrabromo-4,4'-isopropylidenedi phenol	79-94-7	0.050	001
/	227	4,4'-sulphonyldiphenol	80-09-1	0.050	001
/	228	Barium diboron tetraoxide*	13701-59-2	0.005	001
/	229	Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof	-	0.050	001
/	230	Isobutyl 4-hydroxybenzoate	4247-02-3	0.050	001
/	231	Melamine	108-78-1	0.050	001
/	232	Perfluoroheptanoic acid and its salts	-	0.050	001



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/	233	reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4- (1,1,1,2,3,3,3-heptafluoropropan-2-yl)mor pholine and 2,2,3,3,5,5,6,6-octafluoro-4- (heptafluoropropyl)morpholine	-	0.050	001
/	234	Resorcinol	108-46-3	0.050	001

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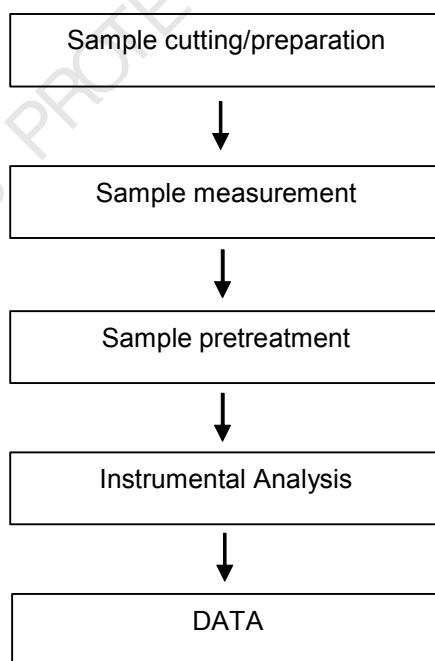
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SVHC Testing Flow Chart



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Test Report (SVHC)

No. CKGEC2200942301

Date: 09 Nov 2022

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Sample photo:



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CERTIFICATE

This is to certify that the Quality Management System of

Xiantao Zefu Protective Products Co., Ltd.

Business License Number: 91429004090580650L

Registered Address: No.3, Chuangye 1st Road, Zhongling IndustryPark, Pengchang Town,
Xiantao City, Hubei Province, China

Audit Address: No.3, Chuangye 1st Road, Zhongling IndustryPark, Pengchang Town,
Xiantao City, Hubei Province, China

applicable to

Production and sales of Isolation gown, Surgeon Cap, Shoe cover; Production and sales of Surgical gown, Lab coat, Patient gown, Coverall, Visitor gown, Pants, Mask, Earphone cover, Disposable caps, Nylon cap, Sleeve cover, Beard cover, Apron, Bed cover, Pillow cover, Disposable gloves, Underpad, Dental bib, Bikini, Drape, Slipper (for export)

has been assessed and registered by POSI against the provisions of

GB/T 42061-2022/ISO 13485:2016

This registration is subject to the company maintaining a Quality Management System,
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Certified organization shall accept regular surveillance audit, the validity of certificates shall
be maintained for the positive result of audit.

Please consult the website: www.posicert.com

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Certificate Registration No: 381190060R2S

Initial issue date: 2019.12.31

Issue date: 2025.12.29

Valid until: 2028.12.28

Shanghai POSI Certification Co., Ltd.

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