

CERTIFICATE OF ANALYSIS

Report No.: GM01-BN21

Product Name	ESA Holder	Specification	Common type
Lot. No.	20220302	Quantity	100000pcs
Mfg. Date	20220302	Exp. Date	20250301
Test Standard	Factory Standard	Report Date	2022.04.15
Item	Technical Requirement	Result	Conclusion
Appearance	The holder is transparent, the surface is smooth, no black spots, no foreign impurities, no flying edges or other injection defects.	Comply	Qualified
Size	The dimension should comply with the specification.	Comply	Qualified
Compliance	The needle holder and blood sampling needle can be fitted well.	Comply	Qualified
Conclusion	Meet the requirement		

Inspector: Tom Li
Date: 2022.04.15

Checker: Leo Sun
Date: 2022.04.15



BOEN HEALTHCARE CO., LTD.

Certificate of Analysis

Product Name:	Blood Collection Needle	Report Date:	2022.04.15	
Specification:	21G x 1 1/2”	Test Qty:	200pcs	
Produce Date:	202202	Batch Qty:	50000pcs	
Lot No.:	22101	Expiry Date:	202701	
Inspection Item	Technique request			Result
Contamination	Observe with normal vision or rectified vision, the surface is cleaning, no contaminate.			pass
Color	The nominal outside diameter color should be same with the color of neilsbed and/or Protection Covers or needle handle.			pass
Connection Fastness	No abruption between needle and neilsbed, after 20N Axial static tension for 10s on the connection			pass
Needle Lumen Smoothness	Lumen should be smooth, under the pressure of 20Kpa, water flow >=21ml			28.9ml
Neilsbed	no apparent burr, bubble or any other defect			pass
Needlepoint	Good puncture force, after enlarge 2.5 times, eyeballing, the needlepoint should be sharp, no burr, no flat top, no hook or any other defect			pass
Rubber Sheath	Good sealing performance, continuously puncture its top for 10 times, there should not be water flows down. No adhesion and break.			pass
Lubricant	There should be no visible accumulation of the lubricant on the needle appearance			pass
Handle of Needle	The handle of Needle should be complete with clear mark. And it should be on the same angle with needlepoint, the gradient shouldn’t larger than 30° .			pass
Plastic Protection Covers	straight, no visible bend; cover should be well fitted with neilbed or the other protection cover, it shouldn't be easy to fall off; Under axial drawing without impact, the separation power <=15N			pass
Puncture Force	<=0.85N			0.561N
Size	The length of connected needle should be no less than 12mm; The length of puncture end should be accord with the technique requirement.			pass
Sterilization	The products should be sterilized by Ethylene oxide.			pass
Ethylene oxide leftover	the leftover per pc <=0.1mg			0.011mg
Conclusion	Pass			

Approver: Zhang Li

Inspector: Li Shanshan



**EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ**

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

BOEN HEALTHCARE CO., LTD
Unit 602, International Center, No.535, Shenxu Road,
Suzhou, 215021, Jiangsu, China

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Blood Collection Needle Holder
UMDNS-Code: [12726]

der Klasse: /
of class: /
de la classe: /
di classe:

I

nach Anhang VIII, Verordnung (EU) 2017/745 / according to annex VIII, Regulation (EU) 2017/745 /
selon l'annexe VIII, le règlement (UE) 2017/745 / secondo l'allegato VIII, regolamento (UE) 2017/745

erfüllt die Anforderungen der Medizinprodukteverordnung (EU) 2017/745 und deren Umsetzungen in nationale Gesetze
entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the requirements of Medical Device Regulation (EU) 2017/745 and its transpositions in national laws which apply
to it. The declaration is valid in connection with the “final inspection report” of the device. /

répond aux exigences du Règlement sur les dispositifs médicaux (UE) 2017/745 et de ses transpositions en droit
national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa i requisiti del Regolamento sui dispositivi medici (UE) 2017/745 e della loro trasposizione nel diritto nazionale
che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Verordnung (EU) 2017/745 Anhang II+III
Regulation (EU) 2017/745 Annex II+III
Réglementation (UE) 2017/745 Annexe II+III
Regolamento (UE) 2017/745 Allegato II+III

Registrier-Nr.: /
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 2021.05.26

Ort, Datum / Place, date /
Lieu, date / Luogo, data

General Manager

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione



EC Declaration of Conformity

Manufacturer: Shandong Chengwu Medical Products Factory
274200 Southern End of Quancheng Road, Chengwu County,
Shandong Province, P.R.China

European Representative: SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam

Product Name: **Disposable sterile venous blood specimen collection needle**

Model: soft-connection; hard-connection

UMDNS Code: 12736

Classification (MDD, Annex IX): **Class IIa, Rule 6**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and All applicable harmonised Standards. All supporting documentations are retained under the premises of the manufacturer.
Shandong Chengwu Medical Products Factory is exclusively responsible for the declaration of conformity

DIRECTIVES

Medical Device Directive:
COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC),
Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Notified Body : TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany

NB Identification number: 0123

(EC) Certificate(s): G2 103129 0002 Rev. 00

Expire date of the Certificate: 2024-02-22

Start of CE Marking: 2019-12-06

Place, Date of Issue:

Signature/date:

Name:

Position:

Wang Jicun

General Manager



Shandong Chengwu 2019.12.06

Wang Jicun 2019.12.06

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets,
Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

A circular blue stamp from TÜV Rheinland LGA Products GmbH is overlaid on a handwritten signature in blue ink that reads "Jason Pan". Below the signature, the text "TÜV Rheinland LGA Products GmbH" and "Tillystraße 2 · 90431 Nürnberg · Germany" is printed.
Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Products: Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Suction Connecting Tubes with Yankauer, Sterile Latex Surgical Gloves, Disposable Surgical Blades & Scalpels With Plastic Handle, Sterile Blood Lancets, Disposable Syringes, Disposable Infusion Sets, Disposable Transfusion Sets, Intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Disposable Tracheal Tubes (Standard & Reinforced), Disposable Oxygen Masks, Non-Rebreathing Masks, Aerosol Masks, Closed Suction Catheters, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Wound Drainage System with and without Trocars, Needle Free Connectors, Digital Thermometers, Humidifier Jar (Bubble Humidifier Jar), Enteral Feeding Sets (Bag);
Aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Disposable

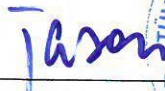
The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15092074 009

Effective date: 2020-11-18

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Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets,
Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

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Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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Blood Collection Needle (Multi-Sample Needle)



Blood Collection Needle (Multi-Sample Needle)

Latex free, multi-sample needles permit several samples to be taken with a single puncture, EO sterile, non toxic, non pyrogenic, polypropylene hubs are color marked.

Cat. No.	Specification	Color	Needle Size	Qty/Case (pcs)
631801	18G	Pink	1"	5000
631802			1 1/2"	5000
631803	20G	Yellow	1"	5000
631804			1 1/4"	5000
631805			1 1/2"	5000
631806	21G	Green	1"	5000
631807			1 1/4"	5000
631808			1 1/2"	5000
631809	22G	Black	1"	5000
631810			1 1/4"	5000
631811			1 1/2"	5000
631812	23G	Blue	1"	5000
631813			1 1/4"	5000
631814			1 1/2"	5000

Blood Collection Needle Holder



Blood Collection Needle Holder

Blood collection needle holder is compatible with Multi-Sample Needle to collecting blood.

Lock the multi-sample needle short end which is with latex cover directly into holder

Insertions finish when you push the white part of the snap.

After collection finished, press the green color button on holder, needle automatically discharge.

Collector can easy finish collection without touch of needle and avoid mistake puncture.

It is non-dangerous products, non-flammable, non-explosive, and can be stored at room temperature.

Cat. No.	Description	Qty/Case(pcs)
632201	Blood Collection Needle holder	4000
632202	Blood Collection Needle holder (safety type)	4000

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Name and address of the manufacturer: / **Unit 602, International Center, No.535, Shenxu Road,**
Nom et adresse du fabricant: / **Suzhou, 215021, Jiangsu, China**
Nome e indirizzo del fabbricante:

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / **Filtered Pipette Tips**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
di classe:

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
(IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B
dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / **Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /**
Conformity assessment procedure: / **EG Annex III (expect point 6) of IVDD 98/79/EC**
Procédure d'évaluation de la conformité: / **Annexe III (sauf le point 6) de l'IVDD 98/79 / CE**
Procedura di valutazione della conformità: **Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**

Registrier-Nr.: /
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

Suzhou, 2022.01.01

Ort, Datum / Place, date /
Lieu, date / Luogo, data

CE

General Manager

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione



Filtered Pipette Tips



Filtered Pipette Tips

Filter pipette tips are used for protection against contamination.

Pipette tips with filter barrier protects pipettors and samples from contamination.

RNase, DNase and Pyrogen Free.

Filtered tips, Filter Tips Pipette, universal and fit most popular brands of pipettors.

Sterile pipette tips.

PP Material, clear color.

Volume: 10ul-1250ul.

Package Style: Bulk: 1000tips/bag, 10bags/ctn

Racked: 96tips/rack, 10racks/pk, 50racks/ctn

Cat No.	Description	Qty/Case(pcs)
640401	Racked filter tips, 96tips/rack, sterile, 10ul	4800
640402	Racked filter tips, 96tips/rack, sterile, 10ul long	4800
640403	Racked filter tips, 96tips/rack, sterile, 20ul	4800
640404	Racked filter tips, 96tips/rack, sterile, 50ul	4800
640405	Racked filter tips, 96tips/rack, sterile, 100ul	4800

640406	Racked filter tips,96tips/rack, sterile, 200ul	4800
640407	Racked filter tips,96tips/rack, sterile, 1000ul	4800
640408	Racked filter tips,96tips/rack, sterile, 1250ul (1000ul long)	4800
640409	Racked filter tips,96tips/rack, sterile, 200ul long	4800
640410	Racked filter tips,96tips/rack, sterile, 300ul	4800
640411	Bulked filter tips,1000tips/bag, sterile, 10ul	10000
640412	Bulked filter tips,1000tips/bag, sterile, 10ul long	10000
640413	Bulked filter tips,1000tips/bag, sterile, 20ul	10000
640414	Bulked filter tips,1000tips/bag, sterile, 50ul	10000
640415	Bulked filter tips,1000tips/bag, sterile, 100ul	10000
640416	Bulked filter tips,1000tips/bag, sterile, 200ul	10000
640417	Bulked filter tips,1000tips/bag, sterile, 1000ul	10000
640418	Bulked filter tips,1000tips/bag, sterile, 1250ul (1000ul long)	10000
640419	Bulked filter tips,1000tips/bag, sterile, 200ul long	10000
640420	Bulked filter tips,1000tips/bag, sterile, 300ul	10000

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Nom et adresse du fabricant: / **Suzhou, 215021, Jiangsu, China**
Nome e indirizzo del fabbricante:

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / **Vacuum Blood Collection Tube**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
di classe:

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
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dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / **Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /**
Conformity assessment procedure: / **EG Annex III (expect point 6) of IVDD 98/79/EC**
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Procedura di valutazione della conformità: **Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**

Registrier-Nr.: /
Registration No.: /
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Benannte Stelle: /
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Organisme notifié: /
Organismo notificato:

CE

Suzhou, 201.05.26

Ort, Datum / Place, date /
Lieu, date / Luogo, data

General Manager

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione



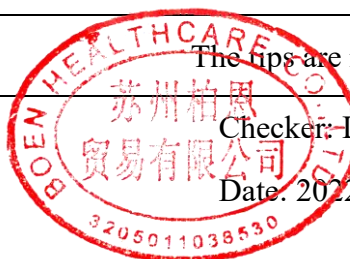
Certificate of Analysis

Report No.: GM07-BN21

Product Name	Filtered Pipette Tips	Product Code	640407
Quantity	4000 racks	Specification	1000μL
Lot. No.	20220301	Mfg. Date	2022-03
Exp. Date	2025-02	Standard	Factory Standard
No.	Item	Technical Requirement	Conclusion
1	Appearance	The surface of tips shall be smooth without obvious deformation, crack, scratch, perforation, impurity, oil stain, bubble and other defects	Comply
		The tips should be uniform color, no obvious color difference.	Comply
		The edges of tips should be flat and smooth, no burr or flying edges.	Comply
		The tips should be straight, with uniform wall thickness, without obvious bending.	Comply
		The filter is installed in place and firmly.	Comply
2	Size	The size should meet the drawings	Comply
3	Performance	The tips are well matched with pipette, it will no fall or leak during use	Comply
4	Biological Requirement	The tips are sterile, Rnase free, Dnase free	Comply
Conclusion		The tips are meet the requirements	

Inspector: Tom Li

Date: 2022.04.15



Checker: Leo Sun

Date: 2022.04.15

Vacuum Blood Collection Tube



Vacuum Blood Collection Tube, EDTA Tube

Material: PET, Glass

Color: Violet

Cat. No.	Specification	Volume	Additive	Qty/case (Glass)	Qty/case (PET)
630801	13×75mm	1ml	EDTAK2	1800	1800
630802	13×75mm	2ml	EDTAK2	1800	1800
630803	13×75mm	3ml	EDTAK2	1800	1800
630804	13×75mm	4ml	EDTAK2	1800	1800
630805	13×75mm	5ml	EDTAK2	1800	1800
630806	13×100mm	5ml	EDTAK2	1200	1200
630807	13×100mm	6ml	EDTAK2	1200	1200
630808	13×100mm	7ml	EDTAK2	1200	1200
630809	16×100mm	10ml	EDTAK2	1200	1200

630901	13×75mm	1ml	EDTAK3	1800	1800
630902	13×75mm	2ml	EDTAK3	1800	1800
630903	13×75mm	3ml	EDTAK3	1800	1800
630904	13×75mm	4ml	EDTAK3	1800	1800
630905	13×75mm	5ml	EDTAK3	1800	1800
630906	13×100mm	5ml	EDTAK3	1200	1200
630907	13×100mm	6ml	EDTAK3	1200	1200
630908	13×100mm	7ml	EDTAK3	1200	1200
630909	16×100mm	10ml	EDTAK3	1200	1200
631001	13×75mm	2ml	EDTANA2	1800	1800
631002	13×100mm	10ml	EDTANA2	1200	1800