1. Renseignements administratifs concernant l'entreprise		***Date de mise à jour :*** 25/02/2025 ***Date d'édition :*** 24/02/2022
1.1	**Nom :** TERUMO FRANCE SAS	
1.2	**Adresse complète :** Bâtiment Atria 1. Avenue Edouard Belin 92500 RUEIL MALMAISON	**Tel:** 0 800 90 50 42 **Fax:** 01 30 96 12 90 **E-mail :** service-client@terumo-europe.com **Site internet :** www.terumo-europe.com
1.3	**Coordonnées du correspondant matériovigilance :** Mme Sabrina Feddag Rarrbo	**Tel :** 0 800 90 50 42 **Fax :** 01 30 96 12 90 **E-mail :** materiovigilancefr@terumo-europe.com
2. Informations sur le dispositif ou équipement		
2.1	**Dénomination commune :** AIGUILLE HYPODERMIQUE	
2.2	**Dénomination commerciale :** Aiguille hypodermique de sécurité AGANI™	
2.3	**Code CLADIMED :** K54AB: Aiguille hypodermique	
2.4	**Code LPPR* (ex TIPS si applicable) :**Non Applicable * « liste des produits et prestations remboursables » inscrits sur la liste prévue à l'article L 165-1	
2.5	**Classe du DM :** IIa **Directive ou règlement de l'UE applicable :** DDM 93/42/CE **selon Annexe n°** II.3 **Numéro de l'organisme notifié :** 0123 (TÜV SÜD Product Service GmbH) **Date de première mise sur le marché dans l'UE :** 2021 **Fabricant du DM : Zhejiang Kindly MedicalDevices Co., Ltd.** No.758, 5th Binhai RoadBinhai Industrial Park, Longwan District325025 Wenzhou, Zhejiang Province PEOPLE'S REPUBLIC OF CHINA La Déclaration de Conformité CE est disponible dans l'annexe I du présent document. Le(s) certificat(s) de marquage CE est (sont) disponible(s) dans l'annexe II du présent document. Le certificat EN ISO 13485 :2016 est disponible dans l'annexe III du présent document.	
2.6	**Descriptif du dispositif :** Les aiguilles hypodermiques de sécurité Agani™, lorsqu'elles sont montées sur une seringue standard Luer-Slip ou Luer-Lock, sont destinées à l'aspiration et à l'injection de liquides à des fins médicales. Après avoir retiré l'aiguille du corps, la gaine de sécurité peut être activée pour couvrir l'aiguille immédiatement après utilisation, afin de limiter les risques de blessures accidentelles par piqûre d'aiguille.	
2.7	**Références Catalogue** : Voir le tableau des spécifications produits disponible dans l'annexe VI du présent document. Voir L'étiquetage disponible dans l'annexe V du présent document	
2.8	**Composition du dispositif et Accessoires** : L'aiguille hypodermique de sécurité AGANI™ est composée de : - une gaine en Polypropylène, - une collerette en Polypropylène, - une embase en Polypropylène, - une canule en acier inoxydable,	

	- une protection en Polypropylène, - une colle époxy et, - un lubrifiant en huile de silicone.
2.9	**Domaine d'utilisation :** Les aiguilles hypodermiques de sécurité Agani™, lorsqu'elles sont montées sur une seringue standard Luer-Slip ou Luer-Lock, sont destinées à l'aspiration et à l'injection de liquides à des fins médicales.
3. Procédé de stérilisation :	
3.1	**DM stérile** : OUI **Mode de stérilisation du dispositif :** Stérilisation à l'oxyde d'éthylène
4. Conditions de conservation et de stockage	
4.1	**Conditions normales de conservation & de stockage :** - Conserver au sec - Dispositif fragile, à manipuler avec précaution - Tenir à l'écart de la lumière du soleil ou d'autres sources lumineuses - Ne pas stocker à des températures extrêmes à l'humidité. Ne pas exposer à la lumière directe du soleil - Non pyrogène. - Ne pas utiliser si l'emballage est endommagé. - Si une aiguille est tordue ou endommagée, ne pas essayer de la redresser ou d'utiliser le produit. - À usage unique. Ne pas réutiliser le produit. Ne pas restériliser le produit. Ne pas retraiter. Un retraitement peut compromettre la stérilité, la biocompatibilité et l'intégrité fonctionnelle de l'appareil. - Système de barrière stérile à usage unique. **Durée de la validité du produit** : Consulter l'étiquette du produit pour la durée de stockage. Ne pas utiliser le dispositif après de la date de péremption indiquée sur l'étiquette. La durée de vie est de 5ans.
5. Sécurité d'utilisation	
5.1	**Sécurité technique** : Se référer aux instructions décrites par le fabricant sur la notice d'utilisation disponible dans l'annexe IV du présent document.
5.2	**Sécurité biologique (s'il y a lieu) :** Se référer aux instructions décrites par le fabricant sur la notice d'utilisation disponible dans l'annexe IV du présent document.
6. Conseils d'utilisation	
6.1	**Mode d'emploi :** Se référer aux instructions décrites par le fabricant sur la notice d'utilisation disponible dans l'annexe IV du présent document.
6.2	**Indications :** Les aiguilles hypodermiques de sécurité Agani™, lorsqu'elles sont montées sur une seringue standard Luer-Slip ou Luer-Lock, sont destinées à l'aspiration et à l'injection de liquides à des fins médicales.
6.3	**Précautions d'emploi :** Se référer aux instructions décrites par le fabricant sur la notice d'utilisation disponible dans l'annexe IV du présent document.
6.4	**Contre- Indications :** Se référer aux instructions décrites par le fabricant sur la notice d'utilisation disponible dans l'annexe IV du présent document.
7. Informations complémentaires sur le produit	
	RAS
8. Liste des annexes au dossier (s'il y a lieu)	

	Annexe I : Déclaration de Conformité CE **Annexe II :** Certificat(s) de marquage CE **Annexe III :** Certificat EN ISO 13485 :2016 **Annexe IV :** Notice d'utilisation **Annexe V :** Etiquetage **Annexe VI :** Spécifications des produits
9. Images (s'il y a lieu)	
	

Annexe I
Déclaration de Conformité CE

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	ZHEJIANG KINDLY MEDICAL DEVICES CO., LTD NO.758, 5TH BINHAI ROAD, BINHAI INDUSTRIAL PARK, LONGWAN DISTRICT, 325025 WENZHOU, ZHEJIANG PROVINCE, PRC.
EUROPEAN REPRESENTATIVE:	SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE) EIFFESTRASSE 80,20537 HAMBURG GERMANY
MEDICAL DEVICE:	SAFETY NEEDLES : 33G, 32G, 31G, 30G, 29G, 28G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G
CLASSIFICATION - *ANNEX IX*:	CLASS IIa, RULE 6
CONFORMITY ASSESSMENT ROUTE:	ANNEX II .3 ,Excluding(4)

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARTION OF CONFORMITY

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	G1 036336 0054 Rev.03
START OF CE-MARKING:	
Valid until:	2024-05-26
PLACE, DATE OF DECLARATION:	Wenzhou 2020-10-27
SIGNATURE:	

浙江康德莱医疗器械股份有限公司
ZHEJIANG KINDLY MEDICAL DEVICES CO.,LTD

POSITION: QUALITY MANAGER

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

ATTACHMENT:

KDL NAME	BRAND NAME	BEVEL	NEEDLE GAUGE	NEEDLE LENGTH(MM)	MODEL NUMBER
SAFETY NEEDLES	TERUMO AGANI SAFETY HYPODERMIC NEEDLE	REGULAR	18G	25mm	SAN1825R1
		REGULAR	18G	38mm	SAN1838R1
		REGULAR	19G	25mm	SAN1925R1
		REGULAR	19G	38mm	SAN1938R1
		REGULAR	20G	25mm	SAN2025R1
		REGULAR	20G	38mm	SAN2038R1
		REGULAR	21G	25mm	SAN2125R1
		REGULAR	21G	38mm	SAN2138R1
		REGULAR	22G	25mm	SAN2225R1
		REGULAR	22G	38mm	SAN2238R1
		REGULAR	23G	25mm	SAN2325R1
		REGULAR	23G	38mm	SAN2338R1
		REGULAR	25G	16mm	SAN2516R1
		REGULAR	25G	25mm	SAN2525R1
		REGULAR	25G	38mm	SAN2538R1
		REGULAR	26G	13mm	SAN2613R1
		REGULAR	27G	13mm	SAN2713R1
		REGULAR	30G	13mm	SAN3013R1

浙江康德莱医疗器械股份有限公司
ZHEJIANG KANGDE MEDICAL DEVICES CO., LTD.

Note: The Table attached is used solely as a reference to prove the conformity of TERUMO AGANI SAFETY HYPODERMIC NEEDLE products listed.

Annexe II
Marquage CE

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 036336 0054 Rev. 03

Manufacturer:

Zhejiang Kindly Medical Devices Co., Ltd.
No.758, 5th Binhai Road
Binhai Industrial Park, Longwan District
325025 Wenzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Disposable Needles, Scalp Vein Sets, Blood-Collecting Needles, Huber Needles, Fistula Needles, Anaesthesia Needles, Dental Needles for Single Use, Sterile I.V. catheter for single use, Disposable Insulin Pen Needle, Sterile Biopsy Needles for single use, Sterile Percutaneous Vertebroplasty Kit for single use, Sterile Irrigation Needles for Single Use, Safety Needles,Safety Scalp Vein Sets, Safety Blood-Collecting Needles, Safety I.V. Catheter for Single Use, Safety Fistula Needles, Luer Adapter, Safety Blood Lancet, Syringes, Infusion Sets, Transfusion Sets, Burette-Type Infusion Sets, Sterile Intravascular Catheter Introducer for Single Use, Sterile Syringes for Insulin for Single Use, Sterile Disinfecting Cap for Single Use.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. 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:G1 036336 0054 Rev. 03

Report No.: BJ20081201

Valid from: 2020-10-27
Valid until: 2024-05-26

Date, 2020-10-27

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

浙江康德莱医疗器械股份有限公司
ZHEJIANG KINDLY MEDICAL DEVICES CO., LTD.

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Zhejiang Kindly Medical Devices Co., Ltd
Manufacturer address and contact details	No.758,5th Binhai Road, Binhai Industrial Park, Longwan District 325000 Wenzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA
Single Registration Number (SRN) (if available)	CN-MF-000007594

Authorised Representative name (if applicable)	Shanghai International Holding Corp. GmbH(Europe)
Authorised Representative address and contact details	Eiffestrasse 80, 20537 Hamburg Germany Phone: +49 89 50084-747
Single Registration Number (SRN) (if available)	DE-AR-000000001

Notified body name (if applicable)	TÜV SÜD Product Service GmbH □ See attached schedule
Notified body number (if applicable)	0123 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 036336 0054 Rev.03 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	2028-12-31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
Actually, our MDR certificate was already obtained with reference to certificate No. G100363360058 Rev.01 and its valid date is from 2022-07-01 to 2026-04-14

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☑ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Zhejiang Kindly Medical Devices Co., Ltd.

Location & Date: Wenzhou, Zhejiang, 2024-03-06

Signature, Print Name, Title: CHEN Hong, Vice Manager of Technology Department

Contact Details (at least email): chenhong@kdlchina.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Disposable Needles (Hypodermic Needles) Basic UDI-DI: Normal type:69230334202002a00401LY Safety type: 69230334202002a00402M2	**Certificate#1: G1 036336 0054 Rev. 03**	**2024-05-26**	**TÜV SÜD Product Service GmbH**	**TÜV SÜD Product Service GmbH**	**2028-12-31**	**N/A**

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

Product Service

Add value.
Inspire trust.

Zhejiang Kindly Medical
Devices Co., Ltd.
Mr. Jianhong Fang
Binhai Industrial Park, Longwan District
No.758, 5th Binhai Road
325025 WENZHOU, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

via Email: kdlzq@126.com

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
36336	713235166 / 713268932 / 713253667	+86-10-6590-6186 jinglin.chen@tuvsud.com	+86-10-6590-6182	2023-08-07	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 036336 0060 Rev. 00

Reference: 713235166 / 713268932 / 713253667

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

Zhejiang Kindly Medical Devices Co., Ltd.
No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District, 325025 Wenzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA
SRN Number: CN-MF-000007594

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3a) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2023-08-07

TÜV SÜD Product Service GmbH
Medical and Health Services

Jeremy Chen

Mr Jinglin Chen
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

F. Eckert

Franziska Eckert
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Disposable Anaesthesia Needle Basic UDI-DI for all variants : Spinal Needles (AN-S I) 6923033420210030070 14U Spinal Needles (AN-S II) 6923033420210030070 24W Epidural Needles (AN-E) 6923033420210030070 34Y Combined Anaesthesia Needles (AN-S/S I) 6923033420210030070452 Combined Anaesthesia Needles (AN-S/S II) 6923033420210030070554 Combined Anaesthesia Needles (AN-E/S II) 6923033420210030070656	☒ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #1; G7 036336 0051 Rev. 01; NB# 0123 Certificate #2; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Scalp Vein Set Basic UDI-DI for all variants: Scalp vein set, normal type, single-wing plate: 69230334202002b00301M8 Scalp vein set, normal type, double-wing plate: 69230334202002b00301M8	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Safety Scalp Vein Set Basic UDI-DI for all variants: Safety scalp vein set, safety type, single-wing plate: 69230334202002b00302MA Safety scalp vein set, safety type, double-wing plate: 69230334202002b00302MA	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Disposable Needle	☐ Class III	☒ N/A	☒ Certification as follows:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: Hypodermic Needle 69230334202002a00401LY	☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	or ☐ Identification of the corresponding device under MDD/AIMDD	Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Safety Needle Basic UDI-DI for all variants: Safety Needle, type 1: 69230334202002a00402M2 Safety Needle, type 2: 69230334202002a00402M2 Safety Needle, type 3: 69230334202002a00402M2	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Blood-Collecting Needle Basic UDI-DI for all variants: Blood Collecting Needle, pen type: 69230334202002a00801ML Blood Collecting Needle, double-wing type: 69230334202002a00801ML Blood Collecting Needle, flashback type: 69230334202002a00801ML Blood Collecting Needle, visible flashback type: 69230334202002a00801ML Blood Collecting Needle, luer adapter: 69230334202002a00801ML Blood Collecting Needle, pen type, with holder: 69230334202002a00801ML Blood Collecting Needle, double-wing type, with holder:	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
69230334202002a00801ML Blood Collecting Needle, flashback type, with holder: 69230334202002a00801ML Blood Collecting Needle, visible flashback type, with holder: 69230334202002a00801ML			
Blood Collecting Needle, luer adapter, with holder: 69230334202002a00801ML	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G2S 036336 0057 Rev. 01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Safety Blood-Collecting Needle Basic UDI-DI for all variants: Safety Blood Collecting Needle, pen type: 69230334202002a00802MN Safety Blood Collecting Needle, double-wing type: 69230334202002a00802MN Safety Blood Collecting Needle, single-wing type: 69230334202002a00802MN Safety Blood Collecting Needle, flashback type: 69230334202002a00802MN Safety Blood Collecting Needle, pen type, with holder: 69230334202002a00802MN Safety Blood Collecting Needle, double-wing type, with holder: 69230334202002a00802MN Safety Blood Collecting Needle, single-wing type, with holder:	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
69230334202002a00802MN			
I.V. Catheter Basic UDI-DI for all variants: I.V. Catheter, pen type: 69230334202002b01801N8 I.V. Catheter, butterfly-wing type 69230334202002b01801N8 I.V. Catheter, scalp vein set type 69230334202002b01801N8	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Safety I.V. Catheter Basic UDI-DI for all variants: Safety I.V. Catheter, pen type: 69230334202002b01802NA Safety I.V. Catheter, butterfly-wing type 69230334202002b01802NA Safety I.V. Catheter, scalp vein set type 69230334202002b01802NA	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Insulin Pen Needle Basic UDI-DI for all variants: Insulin Pen Needle: 69230334202002a01901MY Safety Insulin Pen Needle: 69230334202002a01902N2	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Syringe for Insulin Basic UDI-DI for all variants: Syringe for Insulin, fixed needle: 69230334202002a02401ME Syringe for Insulin, detachable needle: 69230334202002a02402MG	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
Fistula Needle Basic UDI-DI for all variants: Fistula Needle, fixed wing-plate: 69230334202102a02301MY Fistula Needle, rotatable wing-plate: 69230334202102a02301MY	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Safety Fistula Needle Basic UDI-DI for all variants: Safety fistula Needle, fixed wing-plate: 69230334202102a02302N2 Safety fistula Needle, rotatable wing-plate: 69230334202102a02302N2	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dental Needle Basic UDI-DI: 69230334202102a00901NG	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Irrigation Syringe Basic UDI-DI for all variants: Irrigation Syringe, A type, Pull ring type: 69230334202101s06101VB Irrigation Syringe, B type, Push type 69230334202101s06102VD	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G2S 036336 0057 Rev. 01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Irrigation Syringe, C type, Ball capsule type: 69230334202101s06103VF			
Irrigation Needle Basic UDI-DI: 69230334202101s03302V2	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G1 036336 0054 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dispensing Needle Basic UDI-DI for all variants: Dispensing Needle, normal type, without filtering membrane: 69230334202102a04401NK Dispensing Needle, normal type, with filtering membrane: 69230334202102a04401NK Dispensing Needle, safety type, with filtering membrane: 69230334202102a04402NM Dispensing Needle, safety type, without filtering membrane: 69230334202102a04402NM	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate #1; G2S 036336 0057 Rev. 01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Confirmation Letter Revision History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2023/08/07	713235166 / 713268932 / 713253667	Initial issuance

Annexe III
Certificat EN ISO 13485 :2016

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 036336 0056 Rev. 03

Holder of Certificate: **Zhejiang Kindly Medical Devices Co., Ltd.**
No.758, 5th Binhai Road
Binhai Industrial Park, Longwan District
325025 Wenzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design, Development, Production, Sales and Distribution of Sterile Non-active Medical Devices (For detailed information see attachment).**

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:Q5 036336 0056 Rev. 03

Report No.: BJ23081201

Valid from: 2023-11-01
Valid until: 2026-10-31

Date, 2023-10-16

Christoph Dicks
Head of Certification/Notified Body

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 036336 0056 Rev. 03

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies): **Zhejiang Kindly Medical Devices Co., Ltd.**
No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District, 325025 Wenzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Attachment:

Hypodermic Syringe Needles (Sterile Disposable Needles), Butterfly Needles (Sterile Scalp Vein Sets), Infusion and Irrigation Syringes (Sterile Syringes), Infusion Sets (Sterile Infusion Sets), Administration Sets (Sterile Transfusion Sets), Infusion and Irrigation Syringes (Sterile Burette-Type Infusion Sets), Needles for Collection Under Vacuum (Sterile Blood-Collecting Needles), Carpule Needles (Sterile Dental Needles), Spinal and Epidural Anaesthesia Needles (Sterile Anaesthesia Needles), Stopcocks (Sterile Stopcock), Caps without Needle (Sterile Heparin Cap/Stopper), Extensions (Sterile Extension Sets), Needles for Implantable Systems (Sterile Huber Needles), Arteriovenous Fistula (Sterile Fistula Needles), Dental Mirrors and Handles (Sterile Dental Odontotenaculum and Odontoscope), Blood Collection Tubes (Sterile Disposable Vacuum Venous Blood Specimen Collection Containers), Infusion Sets (Sterile Infusion Sets for Single Use), Caps (Sterile Dual-purposed Connector for Single Use), Caps without Needle (Sterile Injection Site for Single Use), Needles for Infusion and Collection (Sterile Drip Chamber for Single Use), Needles for Infusion and Collection (Sterile Piercing Device for Single Use), Infusion and Irrigation Syringes (Sterile Syringes for Single Use), Cannulas and Tips for Aspiration and Irrigation (Sterile Irrigation Needles for Single Use), Peripheral I.V. Catheters (Sterile I.V. catheter for single use), Hypodermic Pen Needles (Sterile Disposable Insulin Pen Needle), Cardiovascular Introducer Sheaths (Sterile Intravascular Catheter Introducer for Single Use), Biopsy Needles (Sterile Biopsy Needles for Single Use), Intraosseous Infusion and Vertebroplasty Infusion Needles (Sterile Percutaneous Vertebroplasty Kit for Single Use), Blunt Needles (Sterile Dispensing Needles for Single Use), Hypodermic Syringe Needles with Safety Systems (Sterile Safety Needles), Butterfly Needles with Safety Systems (Sterile Safety Scalp Vein Sets), Needles for Collection Under Vacuum with Safety Systems (Sterile Safety Blood-Collecting Needles), Peripheral I.V. Catheters with Safety Systems (Sterile Safety I.V. Catheter for Single Use), Arteriovenous Fistula (Sterile Safety Fistula Needles), Needles for Infusion and Collection (Sterile Luer Adapter), Venous Blood Collection Devices (Sterile Safety Blood Lancet), Venous Blood Collection Devices (Sterile Blood Collection Assembly), Irrigation Disposable Syringes (Sterile Irrigation Syringes), Insulin Syringes (Sterile Syringes for Insulin for Single Use), Disinfection Instruments (Sterile Disinfecting Cap for Single Use), Holders for Collection Needles (Blood Collection Sampling Holder).

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

Annexe IV
Notice D’utilisation

FRANÇAIS

CE 0123

TERUMO

Agani AIGUILLE HYPODERMIQUE DE SÉCURITÉ

Non toxique.

L'AIGUILLE HYPODERMIQUE DE SÉCURITÉ Agani est conçue pour l'aspiration et l'injection de fluides à des fins médicales. L'AIGUILLE HYPODERMIQUE DE SÉCURITÉ Agani est compatible avec les seringues Luer-Slip et Luer-Lock standard. Par ailleurs, une fois l'aiguille retirée du corps, la gaine de sécurité peut être activée manuellement pour couvrir l'aiguille immédiatement après utilisation, afin de limiter les risques de blessures accidentelles par piqûre.

AVERTISSEMENTS

- MANIPULER AVEC PRÉCAUTION POUR ÉVITER TOUTE PIQÛRE D'AIGUILLE.
- APRÈS UTILISATION, NE PAS REPLACER LE PROTECTEUR D'AIGUILLE D'ORIGINE.
- À USAGE UNIQUE. JETER IMMÉDIATEMENT CONFORMÉMENT AUX NORMES DE SÉCURITÉ LOCALES.

MISES EN GARDE

- Si une aiguille est tordue ou endommagée, ne pas essayer de la redresser ou d'utiliser le produit.
- Ne pas essayer de désactiver l'appareil de sécurité en forçant l'aiguille hors de la gaine de sécurité.
- À usage unique. Ne pas réutiliser. Ne pas restériliser. Ne pas retraiter. Un retraitement peut compromettre la stérilité, la biocompatibilité et l'intégrité fonctionnelle de l'appareil.

PRÉCAUTIONS D'EMPLOI

- Garder les mains derrière l'aiguille pendant toute la durée d'utilisation et d'élimination.
- Respecter les précautions universelles pour TOUS les patients.
- Ne pas utiliser si l'emballage ou le produit a été endommagé ou contaminé.
- Ne pas stocker à des températures extrêmes et à l'humidité. Ne pas exposer à la lumière directe du soleil.
- L'activation de la gaine de sécurité peut provoquer une légère éclaboussure de liquide pouvant resté sur l'aiguille après l'injection. Par mesure de sécurité, activer la gaine de sécurité en appliquant la méthode à une main, loin de soi et des autres.
- Si, au cours ou à la suite de l'utilisation de cet appareil, un incident grave s'est produit, le signaler au fabricant et/ou à son mandataire agréé, ainsi qu'aux autorités nationales.

MODE D'EMPLOI

1. Sortir avec précaution l'AIGUILLE HYPODERMIQUE DE SÉCURITÉ Agani de son emballage.
2. D'un simple mouvement, visser l'AIGUILLE HYPODERMIQUE DE SÉCURITÉ Agani à la seringue.
3. Relever la gaine de sécurité de l'aiguille en direction du corps de seringue. La gaine de sécurité restera dans la position dans laquelle elle sera placée (Fig. 1).

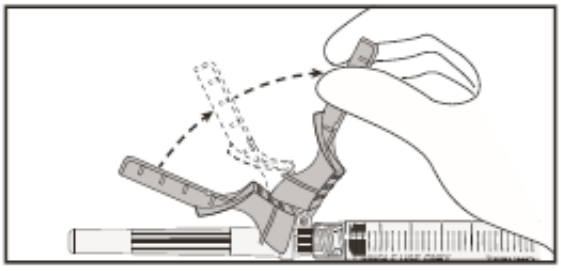


Fig. 1

4. Enlever avec précaution le protecteur d'aiguille afin d'éviter de l'endommager.
5. Effectuer la procédure en respectant le protocole établi.
   Remarque : pour faciliter la manipulation, lorsque l'aiguille est en position « Biseau vers le haut », la gaine se trouve sur le haut.

ACTIVATION

6. Positionner la gaine en préparation de l'activation de l'appareil : en appliquant la méthode à une main, pousser la patte vers l'avant à l'aide d'un doigt ou du pouce, de sorte que la gaine forme avec l'aiguille un angle inférieur à 90 degrés (Fig. 2). REMARQUE : garder en permanence le doigt (le pouce) derrière la patte.

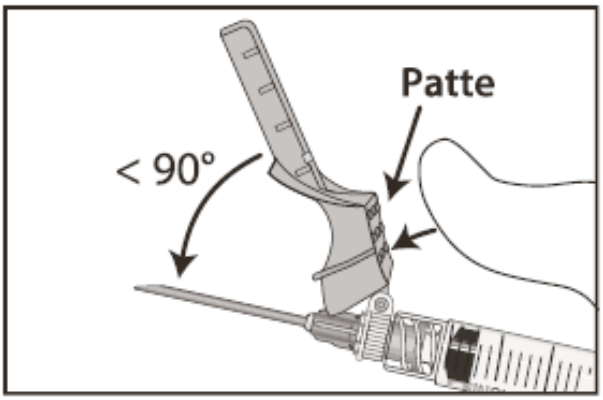


Fig. 2

7. Activer la gaine : positionner la gaine sur une surface plane de façon à former avec celle-ci un angle de 45 degrés environ (Fig. 3A).

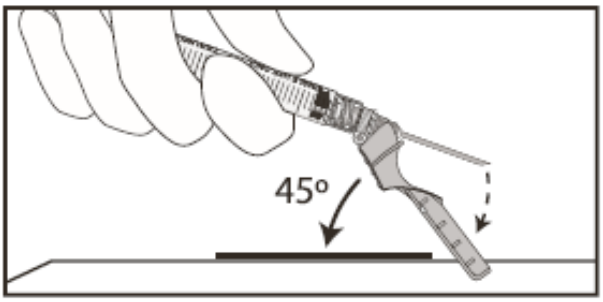


Fig. 3A

Appuyer d'un GESTE FERME et RAPIDE jusqu'à entendre distinctement un CLIC AUDIBLE (Fig. 3B).

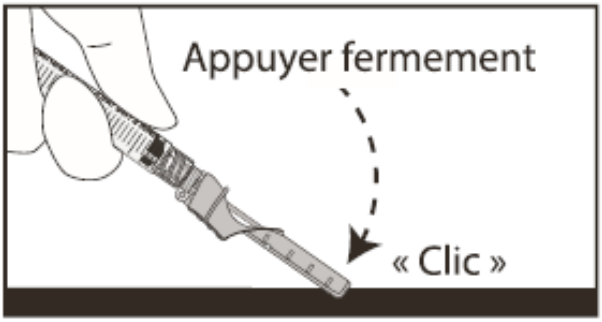


Fig. 3B

VÉRIFIER VISUELLEMENT que l'aiguille est entièrement engagée sous la serrure (Fig. 4).
REMARQUE : en cas d'utilisation d'une aiguille de petit diamètre, le « clic » peut ne pas être audible. Une confirmation visuelle est dès lors requise conformément à la Fig. 4.

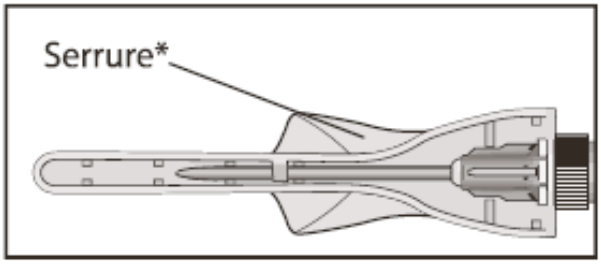


Fig. 4

*Remarque : l'emplacement de la serrure peut varier en fonction de la taille de l'aiguille utilisée.

8. Éliminer les aiguilles et le matériel usagés en respectant les réglementations fédérales et locales en matière d'élimination d'objets tranchants.

Zhejiang Kindly Medical Devices Co., Ltd.
No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District, 325025 Wenzhou, Province de Zhejiang, RPC

EC REP Shanghai International Holding Corp. GmbH (Europe), Eiffestraße 80, 20537 Hambourg, ALLEMAGNE

TERUMO EUROPE N.V., Interleuvenlaan 40, 3001 LOUVAIN, BELGIQUE

	Non pyrogène		Référence du catalogue
	Ne pas réutiliser		Fabricant
	Ne pas restériliser		Représentant autorisé de la Communauté européenne
	Lire le mode d'emploi		Ne pas utiliser si l'emballage est endommagé
	Stérilisé à l'oxyde d'éthylène		Contenu
	Système de barrière stérile à usage unique		Dispositif médical
	Numéro de lot		Date de fabrication
	Date limite d'utilisation		Importateur

08/2020 Rév. 1

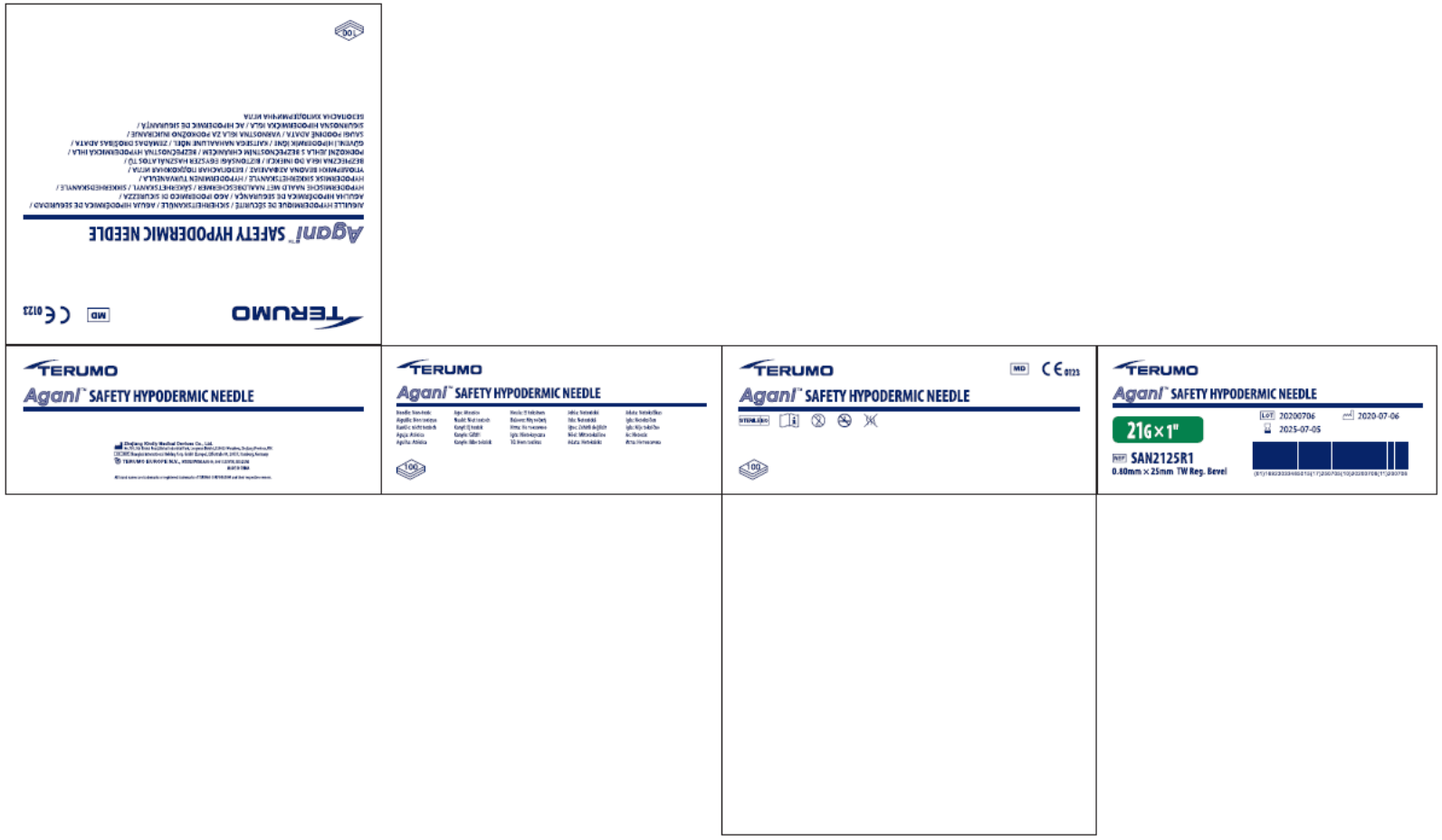
Fabriqué en Chine

Annexe V
Étiquetage

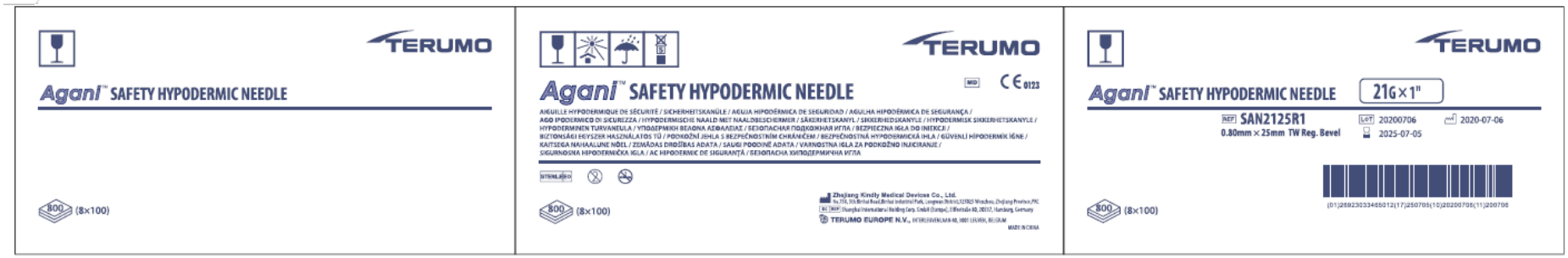
Packaging and labeling
Terumo Agani Safety Hypodermic Needle (Zhejang Kindly Medical Devices Co.Ltd)

Individual Packaging

Inner box labelling



Carton labelling



Terumo Agani Safety Hypodermic Needle_KDL
21 February 2025

Annexe VI
Spécifications des produits

Nom Commercial	Aiguille hypodermique de sécurité AGANI™								
Références	Caractéristiques			Code couleur	Code IUD-ID	Emballage unitaire	UCD	Conditionnement	QML
	Diamètre canule	Longueur canule	Biseau						
SAN1825R1	18 G	25 mm	Standard 11°	Rose	26923033465050	Blister*	100	100 unités/ boîte	800
SAN1838R1	18 G	38 mm	Standard 11°	Rose	26923033465067	Blister*	100	100 unités/ boîte	800
SAN1925R1	19 G	25 mm	Standard 11°	Crème	26923033465074	Blister*	100	100 unités/ boîte	800
SAN1938R1	19 G	38 mm	Standard 11°	Crème	26923033465081	Blister*	100	100 unités/ boîte	800
SAN2025R1	20 G	25 mm	Standard 11°	Jaune	26923033465098	Blister*	100	100 unités/ boîte	800
SAN2038R1	20 G	38 mm	Standard 11°	Jaune	26923033465104	Blister*	100	100 unités/ boîte	800
SAN2125R1	21 G	25 mm	Standard 11°	Vert	26923033465012	Blister*	100	100 unités/ boîte	800
SAN2138R1	21 G	38 mm	Standard 11°	Vert	26923033465029	Blister*	100	100 unités/ boîte	800
SAN2225R1	22 G	25 mm	Standard 11°	Noir	26923033465036	Blister*	100	100 unités/ boîte	800
SAN2238R1	22 G	38 mm	Standard 11°	Noir	26923033465043	Blister*	100	100 unités/ boîte	800
SAN2325R1	23 G	25 mm	Standard 11°	Bleu	26923033465111	Blister*	100	100 unités/ boîte	800
SAN2338R1	23 G	38 mm	Standard 11°	Bleu	26923033465128	Blister*	100	100 unités/ boîte	800
SAN2516R1	25 G	16 mm	Standard 11°	Orange	26923033465135	Blister*	100	100 unités/ boîte	800
SAN2525R1	25 G	25 mm	Standard 11°	Orange	26923033465142	Blister*	100	100 unités/ boîte	800
SAN2538R1	25 G	38 mm	Standard 11°	Orange	26923033465159	Blister*	100	100 unités/ boîte	800
SAN2613R1	26 G	13 mm	Standard 11°	Marron	26923033465166	Blister*	100	100 unités/ boîte	800
SAN2713R1	27 G	13 mm	Standard 11°	Gris	26923033465180	Blister*	100	100 unités/ boîte	800
SAN3013R1	30 G	13 mm	Standard 11°	Jaune	26923033465197	Blister*	100	100 unités/ boîte	800

UCD (Unité de Commande)
CDT (Multiple de l'UCD)
QML (Quantité minimale de livraison)
* Blister : film/papier