Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. ..... din .....

Solicitantul Ericon S.R.L. , cu sediul Durlesti, V. Lupu 6, tel./fax: +373 22 52 01 08 ,+373 6000 6226, e-mail corneliu@ericon.md,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- X-Med Tracheo Set 600/600XXD
- X-Med Tracheo Set 600/600XXDD

Se anexează următoarele acte:

a) declarația de conformitate CE emisă de producător pentru dispozitivul medical fabricat;

b) certificatul de conformitate CE valabil pentru dispozitivele fabricate, după caz;

c) actul prin care producătorul își desemnează reprezentantul.

Data _____ Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: Ericon S.R.L. , cu sediul or. Durlesti, str. Vasile Lupu, nr. 6 , declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- X-Med Tracheo Set 600/600XXD
- X-Med Tracheo Set 600/600XXDD

Sunt autentice și corespund realității.

Corneliu Bunic *Semnătura* _____

Data _____

Mirandola, 12/07/2023

TO WHOM IT MAY CONCERN

LETTER OF AUTHORIZATION

The company **X-MED S.r.l.** (MANUFACTURER)**,** Via Statale Sud, 113 – 41037, Mirandola
VAT IT02704640362

hereby authorizes:

ERICON SRL (DISTRIBUTOR), Vasile Lupu str. Durleşti, Chisinau. Republic of Moldova
VAT XXXXXX

to distribute, in their own name and for their own account the TRACHEO SET (600/600XXE and 600/600XXEP).

Nevertheless, MANUFACTURER is responsible for application of the EU/CE mark and maintaining the products EUDAMED registrations according to MDR 2017/745.
DISTRIBUTOR shall inform MANUFACTURER about all countries the product is intended to be distributed to. DISTRIBUTOR shall act considering the distributor's obligation according to MDR 2017/745 art.14.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical devices.

This authorization is valid for one (1) year and have to be renewed every year by written notice between the parts, unless cancelled by written notice with three (3) months advance notice.

Either Party shall have the right to terminate this Authorization Letter without cause, prior written notice of 30 days.

X-MED S.r.l.
Carlo Alberto Bosi

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31136	Revisione / *Revision*	7
Primo rilascio / *First issue date*	2013-05-07	Valido da / *Valid from*	2018-06-28
Scadenza / *Valid until*	2023-05-06	Ultima modifica / *Last change date*	2021-04-28

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

X-Med S.r.l.

Sede Legale e Operativa / *Registered and operational headquarter:*
Via Statale Sud, 113/B
41037 Mirandola, MO - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Guaine sterili per endoscopi rigidi e flessibili / *Sterile covers for flexible and rigid endoscopes*
Kit chirurgici sterili per tracheostomia / *Sterile surgical kit for tracheostomy*
Kit per manipolazione uterina / *Kit for uterine manipulation*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* del/dated 2021-01-21

Chief Operating Officer
Giampiero Belcredi

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31136	Revisione / *Revision*	7
Primo rilascio / *First issue date*	2013-05-07	Valido da / *Valid from*	2018-06-28
Scadenza / *Valid until*	2023-05-06	Ultima modifica / *Last change date*	2021-04-28

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Guaine sterili per endoscopi rigidi e flessibili / *Sterile covers for flexible and rigid endoscopes*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Marca / *Brandname:*
ENDOSHAFT COVER PLUS-DV

Modello / Model:

Guaine per dosimetri

Codici / Codes:

310/30XXXD

Marca / *Brandname:*
ENDOSHAFT-COVER®, ENDOSHAFT-COVER® PLUS

Modello / Model:

Guaine per otorinolaringoiatria

Codici / Codes:

XXX/ZZZZ(Z)(Z)(Y)

Marca / *Brandname:*
ENDOSHAFT-COVER®-GDK

Modello / Model:

Guaine per ginecologia

Codici / Codes:

XXX/ZZZZ(Z)(Z)(Y)

Marca / *Brandname:*
ENDOSHAFT-COVER®-UDK, ENDOSHAFT-COVER®-UDK FLEX

Modello / Model:

Guaine per urologia

Codici / Codes:

XXX/ZZZZ(Z)(Z)(Y)

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
Giampiero Belcredi

CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31136	Revisione / *Revision*	7
Primo rilascio / *First issue date*	2013-05-07	Valido da / *Valid from*	2018-06-28
Scadenza / *Valid until*	2023-05-06	Ultima modifica / *Last change date*	2021-04-28

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Guaine sterili per endoscopi rigidi e flessibili / *Sterile covers for flexible and rigid endoscopes*

Marca / *Brandname:*
UROTOP® CISTOPRO

Modello / Model:

Guaine per urologia

Codici / Codes:

XXX/ZZZZ(Z)(Z)(Y)

Tipologia / *Medical Devices:*
Kit chirurgici sterili per tracheostomia / *Sterile surgical kit for tracheostomy*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Marca / *Brandname:*
TRACHEO SET

Codici / Codes:

XXX/ZZZZZ(Y)

Tipologia / *Medical Devices:*
Kit per manipolazione uterina / *Kit for uterine manipulation*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Marca / *Brandname:*
ENDOJACK

Codici / Codes:

500/7060, 500/7060E, 500/9080, 500/9080E

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
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E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31136	Revisione / *Revision*	7
Primo rilascio / *First issue date*	2013-05-07	Valido da / *Valid from*	2018-06-28
Scadenza / *Valid until*	2023-05-06	Ultima modifica / *Last change date*	2021-04-28

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Legenda / key
XXX: numero identificativo della famiglia / number that identifies the family
ZZZZZZ: numero / number
Y: lettera identificativa del modello / letter identifying the model
( ): opzionale / optional

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

Mirandola, 04/05/2023

To whom it may concern,

Hereby X-MED S.r.l. informs that the CE certificate comply with Directive 93/42/CEE (Num. di Reg. MED 31136) released on 28/06/2018 by the Notified Body Kiwa Cermet, shall remain valid from the day of its expiry (06/05/2023) until 31/12/2028, being Class I and IIa medical devices. Since the Article 1 of Regulation (UE) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746, it states:

"Regulation (EU) 2017/745 is amended as follows:

1) Article 120 is amended as follows:

a) in paragraph 2, the second subparagraph is replaced by the following:

'Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a of this Article applicable for the relevant risk class of the devices. Certificates issued by notified bodies in accordance with those Directives from 25 May 2017 that were still valid on 26 May 2021 and that have expired before 20 March 2023 shall be considered to be valid until the dates set out in paragraph 3a of this Article only if one of the following conditions is fulfilled:

a) before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;

b) a competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) of this Regulation or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure.';

Paragraph 3a.
Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

a) *31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;*
b) *31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.*

Paragraph 3c.
Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

a) *those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;*
b) *there are no significant changes in the design and intended purpose;*
c) *the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;*
d) *no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);*
e) *no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII."*

Since X-MED S.r.l. has already submitted its application to a Notified Body for the conformity assessment of the produced medical devices and this assessment is currently in progress, as described in Regulation (EU) 2023/607. For which the CE certificate shall remain valid also after its expiry date of 06/05/2023.

Carlo Alberto Bosi
Legale Rappresentante
X-MED S.r.l.

Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2023/06/29
CL1/V3

Esteemed

X-Med S.r.l.

VIA STATALE SUD, 113
41037 Mirandola (MO)

Notified Body Confirmation Letter Reference: MDR 00073

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Kiwa Cermet Italia, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 on NANDO, has 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 following manufacturer:

X-Med S.r.l.
VIA STATALE SUD, 113
41037 Mirandola (MO)

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 the NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under 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 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, by the 20 Mar 2023 for the relevant devices.

The transition timelines 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 (as amended by (EU) 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

On behalf of the Notified Body,
Dr.ssa Frabetti Alessia
Medical Device Division Manager

Table 1: Devices covered by this letter and for which the NB 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 at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Guaine sterili per endoscopi rigidi e flessibili Basic UDI-DI 803398601100CV	Class I devices placed on the market in sterile condition	Same device	Certificate MED 31136; NB 0476
Guaine per urologia Basic UDI-DI 803398601750EA	Class IIa	Same device	Certificate MED 31136; NB 0476
Kit chirurgici sterili per tracheostomia Basic UDI-DI 803398601600DN	Class IIa	Same device	Certificate MED 31136; NB 0476
Kit per manipolazione uterina Basic UDI-DI 803398601500DH	Class IIa	Same device	Certificate MED 31136; NB 0476

Table 2: Devices covered by this letter and for which the NB is NOT 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 at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

Confirmation Letter Revision History

Rev. *Rev.*	Date *Date*	Action *Azione*
0	2023/06/29	Initial issue

For further information on the content of the letter or verification of the validity of the letter please contact medical@kiwa.com or phone at +39.051.4593.111

X-MED MEDICAL DEVICES	**DICHIARAZIONE DI CONFORMITÁ** ***DECLARATION OF CONFORMITY***	**Data: 06/07/2023** **Rev. 11**

Fabbricante: *Manufacturer:*	**X-MED S.r.l.** Via Statale Sud, 113 - 41037 Mirandola (MO) - ITALY
Dispositivo Medico: *Medical Device:*	**TRACHEO SET**
Descrizione: *Description:*	Dispositivo medico sterile, monouso per tracheostomia percutanea dilatativa. *Sterile, single-use medical device for percutaneous dilatative tracheostomy.*
Destinazione d'uso: *Intended use:*	Destinato ad essere utilizzato in procedure di tracheostomia percutanea dilatativa in ambito di Anestesia e Rianimazione. *Intended for use in percutaneous dilated tracheostomy procedures in Intensive Care Units.*
Classificazione Allegato IX: *Classification Annex IX:*	**Classe IIa** (Regola 7 della DDM 93/42/CEE) *Class IIa (Rule 7 MDD 93/42/EEC)*
Percorso di certificazione: *Certification route:*	**Allegato II** della DDM 93/42/CEE *Annex II of the MDD 93/42/EEC*

X-MED S.r.l. dichiara, sotto la propria responsabilità, che il Dispositivo Medico sopra menzionato è conforme ai Requisiti Essenziali della Direttiva Dispositivi Medici 93/42/CEE e s.m.i.. Il Fascicolo Tecnico contenente la documentazione pertinente è conservato presso il Fabbricante e messo a disposizione delle Autorità Competenti e dell'Ente Notificato. X-MED S.r.l. ha sviluppato una procedura per la sorveglianza post-vendita in accordo al Regolamento MDR 2017/745 ed è la sola responsabile della presente Dichiarazione di Conformità.

X-MED S.r.l. declares, under its own responsibility, that the above, mentioned Medical Device is conforming to the essential requirements of the Medical Device Directive 93/42/CEE and subsequent amendments. Technical File and supporting documentation are retained under the premises of the Manufacturer at disposition of the Competent Authorities and Notified Body. The manufacturer is the only responsible for this Declaration of Conformity. X-MED S.r.l. has developed an internal procedure for post-market surveillance of the medical devices according to Regulation MDR 2017/745 and is the sole responsibility of this Declaration of Conformity.

Direttive e Leggi applicabili
Applicable Directives and Laws

- D.Lgs. 46/97 emendato con il D. Lgs 37/10 quale recepimento in Italia della DDM
  D.Lgs. 46/97 amended by D. Lgs 37/10 as transposition in Italy of DDM
- Direttiva CEE 93/42 sui dispositivi medici e s.m.i.
  Council Directive 93/42/EEC and subsequent amendments

Norme europee armonizzate applicabili
Applicable harmonised European standards

L'elenco delle norme applicabili è riportato nel Capitolo 15 del corrispondente Fascicolo Tecnico FT - 04
The list of applicable standards is reported at Chapter 15 of the correspondent Technical File FT - 04.

La presente dichiarazione di conformità è valida fino alla scadenza del certificato CE rilasciato dall'Ente Notificato. Sul certificato di rilascio del prodotto finito il Fabbricante richiama la presente Dichiarazione di Conformità.
The present Declaration of Conformity is valid until the expiry date of CE Certificate released by the Notification Body. It is mentioned also in the release Certificate of finished products issue by the Manufacturer.

XMED MEDICAL DEVICES	**DICHIARAZIONE DI CONFORMITÁ** ***DECLARATION OF CONFORMITY***	**Data: 06/07/2023** **Rev. 11**

Ente Notificato: *Notified Body:*	**KIWA CERMET ITALIA SPA** *Via Cadriano, 23* *40057 Granarolo dell 'Emilia (BO)*	Nr. Ente Notificato: *Nr. Notified Body:*	0476
Certificato Nr.: *Certificate Nr.:*	MED 31136	Data primo rilascio: *First issue date:*	07/05/2013
Valido da: Valid from:	28/06/2018	Ultima modifica Last change date:	28/04/2021 Rev. 7
Scadenza: *Expiry date:*	06/05/2023	Scadenza dichiarazione: *Expiry Declaration:*	06/05/2023

Allegato 1: Elenco codici di vendita e CND / GMDN
(Annex 1: List of codes for sale and CND / GMDN)

Codice (*Codes*) REF	Descrizione (Description)	CND*	GMDN**
600/600XXD 600/600XXDD	Dispositivo medico sterile monouso composto da strumenti chirurgici, medicazioni, tamponi, siringhe, dilatatori, tubi per tracheostomia e altri componenti utilizzati per eseguire procedure di tracheostomia percutanea dilatativa. *Sterile, single-use medical device consisting of surgical instruments, dressings, swabs, syringes, dilators, tracheostomy tubes and other components used to perform percutaneous dilatative tracheostomy procedures.*	R010699	14099

* CND = Classificazione Nazionale italiana dei Dispositivi medici
** GMDN = Global Medical Device Nomenclature

Mirandola, 06/07/2023

Legale Rappresentante
Legal Representative

La presente dichiarazione di conformità è valida fino alla scadenza del certificato CE rilasciato dall'Ente Notificato. Sul certificato di rilascio del prodotto finito il Fabbricante richiama la presente Dichiarazione di Conformità.
The present Declaration of Conformity is valid until the expiry date of CE Certificate released by the Notification Body. It is mentioned also in the release Certificate of finished products issue by the Manufacturer.

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip dispozitiv	Cod GMDN
600/600XXD	TRACHEO SET	TRACHEO SET	HC-HSG7	TRACHEO SET	14099
600/600XXDD	TRACHEO SET	TRACHEO SET	HC-HSG-O7	TRACHEO SET	14099