

FG1993849



CERTIFICATO CE

Certificato n. 1989/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

ANIMUS BEYFORD TRADING, S.L.

29601 MARBELLA - MALAGA - AVDA RAMON Y CAJAL 12, Piso 7 (ESP) - Spain

mantiene nello stabilimento di:

29603 MARBELLA - MALAGA - AVDA. ALFREDO PALMA 24 (ESP) - Spain

un sistema qualità che assicura la conformità dei seguenti prodotti:

Protesi e tubi laringotracheobronchiali in silicone

Modd. Come da documento: "LIST OF CODES REV. 03 - February 2019"; valido solo se provvisto del timbro IMQ.
Marca Stening

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

DM16-0018099-01; DM18-0033612-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2018-03-06
Data aggiornamento: 2019-03-22
Sostituisce: 2018-03-06
Data scadenza: 2023-03-05

IMQ cosign



EC CERTIFICATE

Certificate No 1989/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

ANIMUS BEYFORD TRADING, S.L.

29601 MARBELLA - MALAGA - AVDA RAMON Y CAJAL 12, Piso 7 (ESP) - Spain

manages in the factory of:

29603 MARBELLA - MALAGA - AVDA. ALFREDO PALMA 24 (ESP) - Spain

a quality assurance system ensuring the conformity of the following products:

Laryngotracheobronchial silicone prostheses and tubes

Type ref. As to document: "LIST OF CODES REV. 03 - February 2019"; valid only if provided with IMQ stamp.

Trade mark Stening

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM16-0018099-01; DM18-0033612-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date: 2018-03-06
Updated: 2019-03-22
Substitution Date: 2018-03-06
Expiry Date: 2023-03-05

IMQ

cosign

Av. Alfredo Palma, 24 - Locales 4 y 5
 29603 - Marbella - Málaga - España
 CIF B-9348488-9

LIST OF CODES REV. 03 – February 2019

Description	References	
	Transparent	Radiopaque
TRACHEOBRONCHIAL STENT	STdd-ll	STXdd-ll
BRONCHIAL STENT with side hole	ST-LSDdd-ll	ST-LSDXdd-ll
CONICAL BRONCHIAL STENT	CLASSdd-ll	CLASSXdd-ll
CONICAL BRONCHIAL STENT with side hole	ROLLeadd	ROLLXeadd
SUBGLOTTIC STENT	CLASS-LSDdd-ll	CLASS-LSDXdd-ll
THIN WALL STENT	SGdd-ll	SGXdd-ll
HIGH PRESSURE STENT	HEdd-ll	HEXdd-ll
TRACHEAL STENOSIS STENT	SAPdd-ll	SAPXdd-ll
TRACHEOCARINOBRONCHIAL STENT ("Y" SHAPED)	SETdd-ee	SETXdd-ee
TRACHEOCARINOBRONCHIAL STENT (occlusive)	SYdd-rr-rr	SYXdd-rr-rr
TRACHEAL T-TUBE	SYOdd-rr	SYOXdd-rr
LONG TRACHEAL T-TUBE	TMdd	TMXdd
	TMLdd	TMLXdd
	TMLRdd	TMLRXdd
	TML2dd	TML2Xdd
PEDIATRIC ANGULAR TRACHEAL T-TUBE	TMPAdd	TMPAXdd
PHARYNGEAL TUBE	TFdd	TFXdd
OCCLUSIVE SOLID STENT	--	MS10
		MSeedd
LARYNGEAL STENT	--	LK
		LP
		LM
		LG
LARYNGEAL KEEL	SSll	SSXll
TRACHEOSTOMY CANNULA	CTdd-ll	CTXdd-ll
FENESTRATED TRACHEOSTOMY CANNULA	CTFdd-ll	CTFXdd-ll
TRACHEOSTOMY CANNULA with external branch	CTREdd-ll	CTREXdd-ll
CLASSIC CANNULA	CCdd-ll	CCXdd-ll
TRACHEOSTOMY TUTOR	TUdd	TUXdd

Code nomenclature (lowercase)	meaning
dd	largest diameter in millimeters (from 5 to 20)
ee	smallest diameter in millimeters (from 8 to 14)
rr	branch diameter in millimeters (from 6 to 14)
ll	length in millimeters (from 20 to 110)

Notes:

- Uppercase letters in references codes are fixed, and identify device type.
- Lowercase letters in references codes are variables, and identify different sizes.



ANOTADO EN EL LIBRO INDICADOR
CON EL NÚMERO 1016

TARIO DE MARBELLA

Yo, **LUIS PLÁ RUBIO**, Notario del Ilustre Colegio Notarial de Andalucía, con residencia en Marbella, DOY FE, de que las fotocopias que anteceden concuerdan fielmente con la copia del documento que me exhibe, sin que pueda acreditar la coincidencia de la copia con su respectivo original. Marbella, a ocho de julio de dos mil veinte.

FE PÚBLICA
NOTARIAL

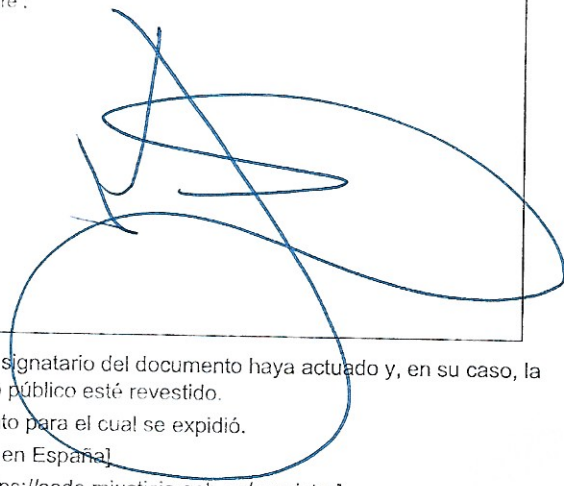


MARBELLA
LUIS PLÁ RUBIO
NOTARIO

[Handwritten signature of Luis Plá Rubio]



TESTIMONIO -FG1993848-

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El presente documento público This public document / Le présent acte public	
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3. quien actúa en calidad de NOTARIO acting in the capacity of agissant en qualité de	
4. y está revestido del sello / timbre de su notaría bears the seal / stamp of est revêtu du sceau / timbre de	
Certificado Certified / Attesté	
5. en Marbella at / à	6. el día 08/07/2020 the / le
7. por D. José Ordóñez Cuadros, con firma delegada del Decano by / par	
8. bajo el número N4263/2020/010847 No sous no	
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