



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



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

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	ST _{dd-ll}	STX _{dd-ll}
BRONCHIAL STENT with side hole	ST-LSD _{dd-ll}	ST-LSDX _{dd-ll}
CONICAL BRONCHIAL STENT	CLASS _{dd-ll} ROLL _{eedd}	CLASSX _{dd-ll} ROLLX _{eedd}
CONICAL BRONCHIAL STENT with side hole	CLASS-LSD _{dd-ll}	CLASS-LSDX _{dd-ll}
SUBGLOTTIC STENT	SG _{dd-ll}	SGX _{dd-ll}
THIN WALL STENT	HE _{dd-ll}	HEX _{dd-ll}
HIGH PRESSURE STENT	SAP _{dd-ll}	SAPX _{dd-ll}
TRACHEAL STENOSIS STENT	SET _{dd-ee}	SETX _{dd-ee}
TRACHEOCARINOBRONCHIAL STENT ("Y" SHAPED)	SY _{dd-rr-rr}	SYX _{dd-rr-rr}
TRACHEOCARINOBRONCHIAL STENT (occlusive)	SYO _{dd-rr}	SYOX _{dd-rr}
TRACHEAL T-TUBE	TM _{dd}	TMX _{dd}
LONG TRACHEAL T-TUBE	TML _{dd} TMLR _{dd} TML2 _{dd}	TMLX _{dd} TMLRX _{dd} TML2X _{dd}
PEDIATRIC ANGULAR TRACHEAL T-TUBE	TMPA _{dd}	TMPAX _{dd}
PHARYNGEAL TUBE	TF _{dd}	TFX _{dd}
OCCLUSIVE SOLID STENT	--	MS10 MS _{eedd}
LARYNGEAL STENT	--	LK LP LM LG
LARYNGEAL KEEL	SS _{ll}	SSX _{ll}
TRACHEOSTOMY CANNULA	CT _{dd-ll}	CTX _{dd-ll}
FENESTRATED TRACHEOSTOMY CANNULA	CTF _{dd-ll}	CTFX _{dd-ll}
TRACHEOSTOMY CANNULA with external branch	CTRE _{dd-ll}	CTREX _{dd-ll}
CLASSIC CANNULA	CC _{dd-ll}	CCX _{dd-ll}
TRACHEOSTOMY TUTOR	TU _{dd}	TUX _{dd}

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.