



EC CERTIFICATE

ProSyS International Ltd

60 Cottenham Park Road
Wimbledon, London SW20 0TB
UK

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4.0) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Manufacture and supply of Laryngectomy Tubes

Device Classification:

IIb

Device Descriptions:

Perforated and Non-Perforated Laryngectomy Tubes

Model Type:

See Attachment 1 of 1

We hereby declare that an examination of the full quality assurance system has been carried out per report **11421504**, following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 1 attachments listing model numbers.

File Number A28478
Certificate No. 823.170104

Cycle Start Date 04 January 2017
Effective Date 04 January 2017
Expiry Date 07 April 2020

Authorised by

Anwen. E. Evans
Certification Manager

For and on Behalf of UL International (UK) Ltd

Notified Body
0843

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom



EC CERTIFICATE

ProSyS International Ltd

60 Cottenham Park Road
Wimbledon, London SW20 0TB
UK

Attachment 1 of 1

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
SpiroTect™ Laryngectomy Tube	Perforated	PTT2001 to PTT2008	Class IIb	12292
	Non-Perforated	PTT 2009 to PTT2016	Class IIb	12292

File Number A28478
Certificate No. 823.170104

Cycle Start Date 04 January 2017
Effective Date 04 January 2017
Expiry Date 07 April 2020

Authorised by

Anwen. E. Evans
Certification Manager

For and on Behalf of UL International (UK) Ltd

Notified Body
0843

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom