



EC CERTIFICATE

ProSys International Ltd

Suite 303
165 Broadway
Highland House
Wimbledon, London SW19 1NE UNITED KINGDOM

Production Quality Assurance System Approval Certificate

Annex V, section 3 of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Manufacture of Faecal Management System

Device Classifications:

Class IIa

Device Descriptions and Model Type:

Please refer to Attachment: 1

We hereby declare that an examination of the production quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex V of Council Directive 93/42/EEC on Medical Devices. We certify that the production 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 V, Section 4. For Class IIb & III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex III is required. This certificate is issued with 1 attachment listing product references covered by this certificate.

File Number A28478
Certificate Number 824.181005
Initial Issue Date January 4, 2017

Cycle Start Date January 4, 2017
Effective Date October 5, 2018
Expiry Date April 7, 2020

Authorised by

Paul Daysh
Medical Notified Body Operations Manager
For and on Behalf of UL International (UK) Ltd



Notified Body
0843

MDD A5 S3 PQ VM
00-MB-S0043 Issue: 15.0

Check Certificate
Status: [here](#)

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



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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
Faecal Management System	Secco Faecal Management System	SEC100+T	Class IIa	17505
	Avantgarde Faecal Management System	AVG100+T	Class IIa	17505

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