



EC CERTIFICATE

ProSyS International Ltd

60 Cottenham Park Road
Wimbledon, London SW20 0TB
UK

Production Quality Assurance System Approval Certificate

Annex V, section 3 of Council Directive 93/42/EEC concerning Medical Devices

Scope of Certificate:

Manufacture and supply of Faecal Management System

Device Classification:

Ila

Device Descriptions:

ProSys Secco Faecal Management System

Model Type:

SEC100-T

We hereby declare that an examination of the production 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 V 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 V, Section 4. For Class IIb & III devices where they are covered by this certificate, an EC Type Examination certificate according to 93/42/EEC, Annex III is required.

File Number A28478
Certificate No. 824.170104

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

Authorised by

Anwen. E. Evans
Certification Manager
and on Behalf of UL International (UK) Ltd

Notified Body
0843

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