Smiths Medical ASD, Inc. **TECHNICAL FILE & CONFORMITY ASSESSMENT**	Document Number: **TF-018 Rev. 005**
Description **Graseby MS Series Drivers and Accessories**	Page 1 of 10

Approval Signatures

Regulatory Affairs: Paula Cord

Signature & Date: Code A 03-JAN-2013

Manufacturing:

Signature & Date (as applicable): Not Applicable - Minor Change

Design Assurance: Tom Hogg Code A 03-JAN-2012

Signature & Date (as applicable):

Microbiology / Sterilization:

Signature & Date (as applicable): Not Applicable - Minor Change

Table of Contents

1 Product Schedule (Reorder Numbers)

Syringe Drivers

Reorder Number	Product Description
0105-0504, 0105-0702, 0105-0711[1], 0105-0712, 0105-0717, 0105-0718, 0105-0725[1], 0105-0748[1], 0105-0755[1]	Graseby Syringe Pumps MS Series, MS 16/A
0113-0001, 0113-0705, 0113-0711[1], 0113-0712, 0113-0717, 0113-0718, 0113-0725[1]	Graseby Syringe Pumps MS Series, MS 26
0113-0707	Graseby Syringe Pumps MS Series, MS 32 French

Accessories

0105-0640	Lock Box
0105-0027	Holster
0105-0108	Syringe Driver Base
0105-0529	Cover

[1] These Graseby Syringe Pump MS Drivers were discontinued from sales and manufacturing April 30, 2012, with service available until April 30, 2017. After the service period is discontinued, the annotated Graseby Syringe Pump MS Drivers will be deleted from the technical file and from the Declaration of Conformity.

2 Classification Sheet

Reorder Number	(Class/rule) MDD 93/42/EEC*	(Class/rule) Australia TGA	(Class/rule) FDA 21 CFR	(Class/rule) Canada SOR/98-282	GMDN	(Class/rule) GHTF/SG1/N15:2006
Syringe Drivers						
0105-0504	IIb / Rule 11	IIb / Rule 11	II / Sec. 880.5725	III / Rule 11 (1)	13215	Class C / Rule 11
0105-0711	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0105-0702	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0105-0712	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0105-0725	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0105-0717	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0105-0718	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0105-0748	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0113-0001	IIb / Rule 11	IIb / Rule 11	II / Sec. 880.5725	III / Rule 11 (1)	13215	Class C / Rule 11
0113-0711	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0113-0705	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0113-0712	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0113-0717	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0113-0718	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0113-0725	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
0113-0707	IIb / Rule 11	N/A	N/A	N/A	13215	Class C / Rule 11
Pump Accessories and Replacement Parts						
0105-0640	I / Rule 12	I / Rule 12	II / Sec. 880.5725	I / Rule 12	16767	Class A / Rule 4

Reorder Number	(Class/rule) MDD 93/42/EEC*	(Class/rule) Australia TGA	(Class/rule) FDA 21 CFR	(Class/rule) Canada SOR/98-282	GMDN	(Class/rule) GHTF/SG1/N15:2006
0105-0027	N/A - Not a Medical Device					
0105-0108	N/A - Not a Medical Device					
0105-0529	N/A - Not a Medical Device					

*as amended by Directive 2007/47/EC

N/A - Does not meet requirements for that specific country. For example, may not meet the country's language requirements and therefore may not be sold in the referenced country.

Classification of medical devices is referenced to the following;

MDD – MedDev 2.4/1 *Guidelines for the Classification of Medical Devices*
Australia TGA – Australian Medical Devices Guidance Document Number 25, *Classification of Medical Devices*
Health Canada – Medical Device Regulations SOR/98-282 Schedule 1 (Section 6)
United States FDA – 21 CFR
GHTF - GHTF/SG1/N15:2006 *Principles of Medical Devices Classification*

3 Device Description

Graseby MS16A, MS 26 MS 32Syringe Drivers

The Graseby MS16A, MS 26 and MS 32Syringe Drivers ("MS Syringe Drivers") are compact devices designed to deliver liquids from syringes with more control and over much longer periods than could be achieved by injecting by hand. The MS syringe drivers are battery powered and utilize screw drive to push the plunger of the installed syringe. Fluid deliver is measured by distance traveled by the plunger. Fluid deliver is continuous.

Indications for Use:

"MS syringe drivers are indicated for fluid deliver as deemed necessary by the healthcare provided."

4 Product Specification

The following are the product specifications for the devices listed in this technical file:

Table 4.1 Device Specifications

Product Specification Number	Description	Reorder Numbers
TS/105-001	Graseby MS16A, MS 26, MS 32 Syringe Drivers	0105-XXXX 0113-XXXX
TS/105-003	Lock Box	0105-640
None, drawing only	Holster	0105-0027
None, drawing only	Syringe Driver Base	0105-0108
None, drawing only	Cover	0105-0529

The contents of each reorder number are listed in their Bill of Materials (BOM).

5 Reference to previous generations or similar devices

The original series of the MS Syringe Drivers were initially distributed in 1979. All designs of the MS Syringe Drivers are similar with functionality nearly identical from one model to the next.

6 FDA Clearances/Approvals:

510(k) Notification Number	Date Cleared	Product Name
K802400	16 Dec 1980	MS16A Syringe Driver
K830423	07 Mar 1983	MS16A Syringe Driver

7 Essential Requirements Checklist

ER-035 provides documented evidence of conformity to the Medical Directive Annex I for the Graseby MS16A, MS 26, MS 32 Syringe Drivers. (Please see St. Paul Standard Operating Procedure RA001 for the Essential Requirements Checklist procedure)

8 Risk Analyses and Control Summary

Risks associated with the release and use of the MS Syringe Drivers have been evaluated and mitigated by the product development process.

As the MS Syringe Drivers were initially developed prior to ISO 14971, only subsequent design considerations have been reviewed against this standard. The products have been fully validated against their design requirements for their intended use.

Document	Description / Conclusion	Location
RA002/01	The risks associated with the use of the MS Syringe Drivers were deemed acceptable when weighed against the benefit to the patient	R&D Office, Luton

9 Product Verification and Validation

The Graseby MS16A, MS 26 MS 32 Syringe Drivers were subjected to verification and validation testing. The verification and validation testing performed demonstrate the devices function as intended and perform to specification. A list of testing performed is included in the Essential Requirements Checklist ER-035.

10 ESD and EMC Testing Summary

The Graseby MS16A, MS 26, MS 32Syringe Drivers are battery powered electronic devices. These devices do not contain integrated circuitry or is device function controlled by software. To evaluate its electromagnetic compatibility (EMC) for both emissions and immunity, Smiths Medical ASD, Inc. ("Smiths") conducted extensive EMC and ESD testing on the syringe drivers. A list of EMC and ESD testing performed on the device is included in the Essential Requirements Checklist ER-035.

11 Sterilization

The Graseby MS16A, MS 26, MS 32 Syringe Drivers and related accessories are not sterilized.

12 Biocompatibility

The Graseby MS16A, MS 26, MS 32 Syringe Drivers external housings are constructed of materials similar to other medical devices which have been shown to be non-reactive on the basis that no complaints have been received due to allergic reactions associated with the pump's use.

13 Software Verification and Validation

Not applicable to the Graseby MS16A, MS 26, MS 32 Syringe Drivers.

14 Biological Safety

The Graseby MS16A, MS 26, MS 32 Syringe Drivers are designed to promote safe and effective use. The exterior housing of the devices have smooth surfaces and sharp edges are minimized. The User Interface is designed to be intuitive and easily manipulated per the accompanying instructions for use.

15 Animal Studies

No animal studies were conducted on the subject devices.

16 Medicinal Substances

There are no medicinal substances shipped with the subject devices.

17 Clinical Evidence

A Clinical Date Review was conducted for the subject devices and is referenced in the Essential Requirements Checklist ER-035.

18 Design and Manufacturing

Manufacturing Processes:
The manufacturing process for each reorder number is controlled by their Bill of Materials (BOM). Please see each individual BOM for a complete list of manufacturing processes.

Design Authority:

Smiths Medical ASD, Inc.
1265 Grey Fox Road
St. Paul, MN 55112 USA

Manufacturing:

Smiths Medical International Ltd.
Bramingham Business Park,
Enterprise Way, Luton,
Bedfordshire, LU3 4BU, UK

Key Suppliers:

Supplier	Description
Pensar Electronic Solutions 2222 East Pensar Drive Appleton, WI 554911	PCBA (PWA), Main Board

19 Labeling

The labeling for each reorder number is controlled by their respective Bill of Materials (BOM). The BOM is control by procedure

Labeling development, review and approval is controlled by written procedures to ensure conformity to regulatory requirements. Labeling is controlled by procedure DP-EN-03 *Document/Data Control: Change Control.*

20 Packaging

The packaging for each reorder number is controlled by their respective Bill of Materials (BOM). The BOM is control by procedure DP-EN-02 *Document/Data Control: Document Approval Procedure.*

The Graseby Syringe Drivers and Accessories were subjected package testing. The testing performed demonstrated the packaging performed to specifications. A list of package testing is included in the Essential Requirements Checklist ER-035.

21 Declaration of Conformity

The Declaration of Conformity is kept in the Smiths Medical ASD, Inc. St. Paul Regulatory Affairs department.

22 Revision History

Revision	Effective Date	Reason
Rev. 001	16 Mar, 2009	New ER Checklist and Technical File Format
Rev. 002	16 Feb, 2010	Minor Change - Update for the name change from MD to ASD, Update template
Rev. 003	19 Mar, 2010	Minor Change – Removed reference to the MS18. Does not comply with the Directive
Rev. 004	21 July, 2010	Minor Change – updated manufacturing site from Watford to Luton
Rev. 005		Minor Change – added annotation to Section 1, Product Schedule, due to the discontinuation of sales and manufacture of specific MS Drivers. They will continue to be included with this Technical File until their service period ends in 2017.