GRASEBY

PRODUCT SPECIFICATION

and

VERIFICATION/VALIDATION REPORT

for

SYRINGE DRIVERS

TYPES: MS16A, MS18, MS26 and MS32

(Ambulatory Syringe Infusion Pumps)

Product Family 002

Product Manager:	Date:
Code A	9/10/01
Technical <u>Executive Product Supp</u> ort:	Date:
Code A	7 (ιο/ ο (
Quality Assurance and Regulatory Affairs:	Date:
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Issue	Date and a second	Reason for Issue the transmission of the second states and the
A	16/03/98	First issue.
В	26/11/98	Addition of foreign language variants - see Table on pages 4 & 5.
С	12/01/99	Addition of Deltec Variant MS16A.
D	09/10/01	Addition of Lock-box to spares list.

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1. Introduction

Syringe drivers and pumps are medical devices for delivering liquids from syringes with more control and over much longer periods than could be achieved by injecting by hand. This gives the possibility for a wider choice of treatments to be used. The **Syringe Drivers Types MS16A, MS18, MS26** and **MS32** (the Drivers) are simple to operate, battery powered, devices for ambulatory use.

2. Scope

This specification defines the intended purpose of the Drivers listed and gives the requirements for their; characteristics, performance, construction, labelling, packaging, documentation, maintenance and regulatory compliance.

Syringe Driver Type MS16A	0105-0504
Syringe Driver Type MS18	0112-0002
Syringe Driver Type MS26	0113-0001
Syringe Driver Type MS32	0113-0707

Where differences exist in the specification of the Drivers these are shown with an accompanying reference to the type number.

Foreign language variants

MS16A	Italian French Dutch Spanish Norwegian German Swedish Finnish Danish Greek USA	0105-0711 0105-0702 0105-0712 0105-0725 0105-0715 0105-0717 0105-0718 0105-0742 0105-0744 0105-0748 0105-0750
MS18	Italian Greek	0112-0711 0112-0748
MS26	Italian French Dutch Spanish Norwegian	0113-0711 0113-0705 0113-0712 0113-0725 0113-0715

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	German	0113-0717	
	Swedish	0113-0718	
	Finnish	0113-0742	
 	Danish	0113-0744	
	Greek	0113-0748	
MS32	French	0113-0707	

3. References

The following standards form part of this specification by reference:

EN 60601-1:1990 Medical electrical equipment - Part 1: General requirements for safety.

EN 60601-1-2:1993 Medical electrical equipment - Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests.

EN 30993-1:1994 Biological evaluation of medical devices - Part 1: Guidance on selection of tests.

EN 980:1996 Graphical symbols for use in the labelling of medical devices.

This Standard supports the essential requirements of EC Directive 93/42/EEC.

EN 20780:1993 Packaging - Pictorial marking for handling of goods.

4. Description

The Drivers are power driven devices that push the plunger of a syringe fitted directly onto them forward at a constant controlled rate. The Drivers are small, light and battery powered so they can be carried around by patients whilst they are undergoing treatment. The different Drivers cover a range of delivery rates and times.

The rate of the Drivers is set in **millimetres** per hour or 24 hours, with the exception of the MS32 where the rate is set in **millilitres** per hour and is used with a B-D PLASTIPAK 20 ml syringe.

All the Drivers share a common enclosure and electromechanical drive components.

5. Intended purpose of the devices

To be used for administering medication, as liquids, from most of the syringe brands and sizes from 2 ml up to 35 ml capacity. By the epidural, intra-arterial, intravenous, intramuscular or subcutaneous routes. The Drivers are suitable for ambulatory use.

They are to be used under medical supervision.

The intended purpose of each type is shown in Table 1.

Туре	Infusion time	Rate
MS16A	30 min to 24 h	0 - 99 mm/h in 1 mm/h steps
MS18	12 h	5 mm/h fixed
MS26	24 h to 60 d	0 - 99 mm/24h in 1 mm/24h steps with on demand user boost
M\$32	volumetric	0 - 9,9 ml/h in 0,1 ml/h steps B-D PLASTIPAK 20 ml syringe only

Table 1

The Drivers are not suitable for:

- 1. Use for infusing medication where pulsatile delivery action is unacceptable.
- 2. Use in environments with flammable gas mixtures or with oxygen enriched atmospheres.
- 3. Use in strong magnetic fields, for example; NMR scanners.

6. Characteristics

6.1 Controls

6.1.1 \$	Start			
Defines	the user controls provid	ded to start the device	e operating and test the correct on	eration of the device alarm systems
Ref		Specificat	ion	Verification/Validation
6/1	Start/test	MS16A MS18 MS32	Push to test. Release to start.	Verification: Confirmed by review of General Assemblies (GAs); 0105-0501, 0112-0001 and 0113-0707. [12/3/98 CW] Validation: Confirmed by inspection of examples of production Drivers; MS16A, MS18 and MS32. [12/3/98 CW]
6/2	Start/boost/test	MS26	Push to boost or test. Release to start.	Verification: Confirmed by review of GA 0113-0002. [12/3/98 CW] Validation: Confirmed by inspection of example of a production Driver, MS26. [12/3/98 CW]
6.1.2 \$	Stop the user controls provid	led to stop the device	operating.	
Ref	Ref Specification		ion	Verification/Validation
6/3	3 Stop Automatical syringe is e force is exc runs.		tomatically switches off when ringe is empty, maximum drive ce is exceeded or motor over- ns.	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW] Validation: Confirmed by inspection of examples of production Drivers; MS16A, MS18, MS26 and MS32. [12/3/98 CW]
6.1.3 F	Rate he user controls provid	led to set the delivery	rate of the device.	J
Ref	Ref Specification		ion	Verification/Validation
6/4	Set rate	MS16A MS26 MS32	Two ten position rotary switches. Tool required to operate switches.	Verification: Confirmed by review of GAs; 0105-0501, 0113-0002 and 0113-0707.[12/3/98 CW] Validation: Confirmed by inspection of examples of production Drivers; MS16A, MS26 and MS32. [12/3/98 CW]
6/5	Fixed rate	MS18	No controls.	Verification: Confirmed by review of GA 0112-0001, [12/3/98 CW]
		·····		

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		Validation: Confirmed by inspection of example of a production Driver, MS18. [12/3/98 CW]
6.1.4 S	yringe plunger position	
Defines tl	ne user controls available to move the syringe driving mechanism of the devi	ce.
Ref	Specification	Verification/Validation
6/6	Single release control allowing manual adjustment of the syringe plunger position with one hand.	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
		Validation: Confirmed by inspection of examples of production Drivers; MS16A, MS18, MS26 and MS32. [12/3/98 CW]

6.2 Alarms and indications

6.2.1	6.2.1 Audible					
Defines	the audible alarms and	indications given by t	he device.			
Ref	tef Specification			Verification/Validation		
6/7	Driver stops	MS16A MS26 MS32	Audible tone	Verification: Confirmed by review of GAs; 0105-0501, 0113-0002 and 0113-0707.[12/3/98 CW] Validation: Confirmed by inspection of examples of production Drivers; MS16A, MS26 and MS32. [12/3/98 CW]. Lock-box effects detailed within LR/105-004-A.		
6/8	Test finished	MS16A MS26 MS32	Audible tone	Verification: Confirmed by review of GAs; 0105-0501, 0113-0002 and 0113-0707.[12/3/98 CW] Validation: Confirmed by inspection of examples of production Drivers; MS16A, MS26 and MS32. [12/3/98 CW]. Lock-box effects detailed within LR/105-004-A.		
6/9	Motor over-runs	MS16A MS26 MS32	Audible tone	Verification: Confirmed by review of GAs; 0105-0501, 0113-0002 and 0113-0707.[12/3/98 CW] Validation: Confirmed by inspection of examples of production Drivers; MS16A, MS26 and MS32. [12/3/98 CW]. Lock-box effects detailed within LR/105-004-A.		
6/10	Boost dose	MS26	Audible tones	Verification: Confirmed by review of GA 0113-0002. [12/3/98 CW] Validation: Confirmed by inspection of example of a production Driver, MS26. [12/3/98 CW]. Lock-box effects detailed within LR/105-004-A.		

6.2.2	Visual			
Defines	the visual alarms and in	dications given by the	device.	
Ref		Specificatio	n	Verification/Validation
6/11	Driver operating	Flashing light. The flash period allows the drive control system function to be confirmed.		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
				Validation: Confirmed by visual inspection of examples of production Drivers; MS16A, MS18, MS26 and MS32. [12/3/98 CW]
6/12	Test finished	'Driver operating' light extinguishes		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
**************************************				Validation: Confirmed by visual inspection of examples of production Drivers; MS16A, MS18, MS26 and MS32. [12/3/98 CW]
6/13	Driver stops	'Driver operating' light extinguishes		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
				Validation: Confirmed by visual inspection of examples of production Drivers; MS16A, MS18, MS26 and MS32. [12/3/98 CW]
6/14	Motor over-runs	'Driver operating	light extinguishes	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
				Validation: Confirmed by visual inspection of examples of production Drivers; MS16A, MS18, MS26 and MS32. [12/3/98 CW]
6/15	Battery power low	MS16A	'Driver operating' light	Verification: Confirmed by review of GAs; 0105-0501, 0113-0002 and 0113-0707.[12/3/98 CW]
,		MS26 MS32	intensity fades	Validation: Confirmed by inspection of examples of production Drivers; MS16A, MS26 and MS32. [12/3/98 CW]
6/16	Set rate mm/h	MS16A	Numerals 0 to 9 for	Verification: Confirmed by review of GA 0105-0501. [12/3/98 CW]
			tens and units digits	Validation: Confirmed by inspection of example of a production Driver, MS16A. [12/3/98 CW]
6/17	5 mm/h	MS18	Marked 5 mm/h	Verification: Confirmed by review of GA 0112-0001. [12/3/98 CW]
				Validation: Confirmed by inspection of example of a production Driver, MS18. [12/3/98 CW]
6/18	Set rate mm/24h	MS26	Numerals 0 to 9 for	Verification: Confirmed by review of GA 0113-0002. [12/3/98 CW]
			tens and units digits	Validation: Confirmed by inspection of example of a production Driver, MS26. [12/3/98 CW]
6/19	Set rate ml/h	MS32	Numerals 0 to 9 for	Verification: Confirmed by review of GA 0113-0707. [12/3/98 CW]
			units and tenths digits	Validation: Confirmed by inspection of example of a production Driver, MS32. [12/3/98 CW]

6.3 Syringe attachment

6241		
0.3.1 3	security	
Defines	the parts of the syringe that are secured for safe operation by the device.	1
Ref	Specification	Verification/Validation
6/20	Syringe barrel	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
		Validation: Confirmed by visual inspection and functional evaluation of representative examples of production Drivers, MS26 SN 27143 and MS32 SN 28643. / Equipment used: Syringes; B-D PLASTIPAK 2, 5, 10, 20 (16,5 max.) mf, B Braun Omnifix 2, 5, 10, 20 (19 max.), 30 (22 max.) ml, Sherwood monoject 5, 10, 20 (17 max.) ml, Terumo 20 (17 max.), 30/35 (22 max.) mi. [12/3/98 CW]
		Effects of Lock-box validated within VR105-003-A.
		Note: MS16A, MS18, MS26 and MS32 have a common enclosure and mechanical layout
6/21	Syringe finger grips	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
		Validation: Confirmed by visual inspection and functional evaluation of representative examples of production Drivers, MS26 SN 27143 and MS32 SN 28643. / Equipment used: Syringes; B-D PLASTIPAK 2, 5, 10, 20 (16,5 max.) ml, B Braun Omnifix 2, 5, 10, 20 (19 max.), 30 (22 max.) ml, Sherwood monoject 5, 10, 20 (17 max.) ml, Terumo 20 (17 max.), 30/35 (22 max.) ml. [12/3/98 CW]
		Effects of Lock-box validated within VR105-003-A.
6/22	Syringe plunger push-button	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
		Validation: Confirmed by visual inspection and functional evaluation of representative examples of production Drivers, MS26 SN 27143 and MS32 SN 28643. / Equipment used: Syringes; B-D PLASTIPAK 2, 5, 10, 20 (16,5 max.) ml, B Braun Omnifix 2, 5, 10, 20 (19 max.), 30 (22 max.) ml, Sherwood monoject 5, 10, 20 (17 max.) ml, Terumo 20 (17 max.), 30/35 (22 max.) ml. [12/3/98 CW]
		Effects of Lock-box validated within VR105-003-A.

6.4 Power supply

6.4.1 E	6.4.1 Battery				
Defines !	the battery size and type for powerir	ig the device.			
Ref	Sp	ecification	Verification/Validation		
6/23	Single 9 volt primary alkaline battery	IEC 6LR61 or 6LF22	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]		
			Validation: Confirmed by visual inspection of examples of production Drivers; MS16A, MS18, MS26 and MS32. [12/3/98 CW]		
6/24	Installing battery with polarity reve	ersed causes no damage.	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]		
			Validation: Confirmed by inspection of examples of production Drivers; MS16A, MS18, MS26 and MS32. No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]		

7. Performance

7.1 Physical

7.1.1 Rate

Defines the delivery rate range of the device.

Ref		Specification		Verification/Validation
	Rate	Steps	Туре	
7/1	0 to 99 mm/h	1 mm/h	MS16A	Verification: Confirmed by review of GA 0105-0501. [12/3/98 CW]
				Validation: Confirmed by inspection of test record of production Driver, MS16A SN 41233. [12/3/98 CW]
7/2	5 mm/h	fixed	MS18	Verification: Confirmed by review of GA 0112-0001. [12/3/98 CW]
				Validation: Confirmed by inspection of test record of production Driver, MS18 SN 21200. [12/3/98 CW]
7/3	0 to 99 mm/24h	1 mm/24h	MS26	Verification: Confirmed by review of GA 0113-0002. [12/3/98 CW]
				Validation: Confirmed by inspection of test record of production Driver, MS26 SN 27143. [12/3/98 CW]
7/4	Boost	0,23 mm/audible tone	MS26	Verification: Confirmed by review of GA 0113-0002. [12/3/98 CW]
				Validation: Confirmed by inspection of test record of production Driver, MS26 SN 27143. [12/3/98 CW]
7/5	0 to 9,9 ml/h	0,1 ml/h	MS32	Verification: Confirmed by review of GA 0113-0707. [12/3/98 CW]
•••••				Validation: Confirmed by inspection of test record of production Driver, MS32 SN 28643. [12/3/98 CW]
7.1.2 [Prive accuracy			
Defines t	he accuracy of the linear	r drive mechanism that pushes	the syringe plunge	r forward.
Ref		Specification		Verification/Validation
7/6	±5%			Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707.

Validation: Confirmed by inspection of test records of production Drivers; M\$16A SN 41233, M\$18 SN 21200, M\$26 SN 27143 and M\$32 SN 28643. [12/3/98 CW]

[12/3/98 CW]

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7.1.3	Drive force		
Ref	Specification		Verification/Validation
7/7	30 N to 50 N		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
			Validation: Confirmed by inspection of test records of production Drivers; MS16A SN 41233, MS18 SN 21200, MS26 SN 27143 and MS32 SN 28643. [12/3/98 CW]
7.1.4 \$	Syringe sizes		
Defines accomm	the range of syringe sizes that the odated.	device can be used with. Son	ne sizes may not be able to be filled to their designated capacity. Some brands may not be
Ref	Specification		Verification/Validation
7/8	2 ml to 35 ml	MS16A MS18 MS26	 Verification: Confirmed by review of GAs; 0105-0501, 0112-0001 and 0113-0002. [12/3/98 CW] Validation: Confirmed by visual inspection and functional evaluation of representative examples of production Drivers, MS26 SN 27143. / Equipment used: Syringes; B-D PLASTIPAK 2, 5, 10, 20 (16,5 max.) ml, B Braun Omnifix 2, 5, 10, 20 (19 max.), 30 (22 max.) ml, Sherwood monoject 5, 10, 20 (17 max.) ml, Terumo 20 (17 max.), 30/35 (22 max.) ml. [12/3/98 CW] Note: MS16A, MS18, MS26 and MS32 have a common enclosure and mechanical layout
7/9	20 ml B-D PLASTIPAK, with scale 20 ml = 70 mm	MS32	Verification: Confirmed by review of GA 0113-0707. [12/3/98 CW] Validation: Confirmed by visual inspection and functional evaluation of an example of a production Driver, MS32 SN 28643. / Equipment used: Syringe, B-D PLASTIPAK 20 (16,5 max.) ml. [12/3/98 CW]

7.1.5	7.1.5 Audible indicator				
Ref		Specification	Verification/Validation		
7/10	Frequency	3 kHz ± 0,5 kHz	Verification: Confirmed by review of GAs; 0105-0501, 0113-0002 and 0113-0707. [12/3/98 CW]		
			Validation: Awaiting validation by measurement when suitable equipment is available.		
7/11	Duration	5 s to 20 s	Verification: Confirmed by review of GAs; 0105-0501, 0113-0002 and 0113-0707. [12/3/98 CW]		
			Validation: Confirmed by inspection of test records of production Drivers; MS16A SN 41233, MS26 SN 27143 and MS32 SN 28643. [12/3/98 CW]		
7/12	Volume	Audible at 1 m with normal or corrected hearing.	Verification: Confirmed by review of GAs; 0105-0501, 0113-0002 and 0113-0707. [12/3/98 CW]		
			Validation: Confirmed by inspection of test records of production Drivers; MS16A SN 41233, MS26 SN 27143 and MS32 SN 28643. [12/3/98 CW]		

Ref		Speci	fication		Verification/Validation
7/13	Yellow light. (Green o Variant MS16A).	on Deltec	MS16A MS26 MS32		Verification: Confirmed by review of GAs; 0105-0501, 0113-0002 and 0113-0707.[12/3/98 CW Validation: Confirmed by visual inspection of examples of production Drivers; MS16A, MS26 and MS32. [12/3/98 CW]
7/14	Red light		MS18		Verification: Confirmed by review of GA 0112-0001. [12/3/98 CW] Validation: Confirmed by visual inspection of an example of a production Driver, MS18. [12/3/98 CW]
7/15	Flash period	1,05 s	± 2%	MS16A	Verification: Confirmed by review of GA 0105-0501. [12/3/98 CW] Validation: Confirmed by inspection of test record of production Driver, MS16A SN 41233. [12/3/98 CW]
7/16	Flash period	1,93 s	± 4%	MS18	Verification: Confirmed by review of GA 0112-0001. [12/3/98 CW] Validation: Confirmed by inspection of test record of production Driver, MS18 SN 21200. [12/3/98 CW]
7/17	Flash period	25,2 s	± 2%	MS26	Verification: Confirmed by review of GA 0113-0002. [12/3/98 CW] Validation: Confirmed by inspection of test record of production Driver, MS26 SN 27143. [12/3/98 CW]
7/18	Flash period	3 s	± 2%	MS32	Verification: Confirmed by review of GA 0113-0707. [12/3/98 CW] Validation: Confirmed by inspection of test record of production Driver, MS32 SN 28643. [12/3/98 CW]
7/19	Battery low level	7,0 V	to 5,5 V	MS16A MS26 MS32	Verification: Confirmed by review of GAs; 0105-0501, 0113-0002 and 0113-0707.[12/3/98 CW] Validation: Confirmed by inspection of test records of production Drivers; MS16A SN 41233, MS26 SN 27143 and MS32 SN 28643. [12/3/98 CW]
7.1.7 E	Battery life	vill operate with		ory of the enceified	tuno
Ref		Speci	fication	ery of the specified	Verification/Validation
7/20	50 full deliveries	.			Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707.

[12/3/98 CW]

Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]

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7.1.8	Chemical resistance	
Defines	he chemicals that must not affect the other performance requirements, when	the device is used as intended.
Ref	Specification	Verification/Validation
7/21	The performance of the Driver is unaffected by substances that come into contact with it in normal use.	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
		Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]
7.1.9 F	Packaging performance	
Defines (hat the packaging protects the devices and maintains their intact state, when	transported and stored as advised.
Ref	Specification	Verification/Validation
7/22	The specified performance of the Driver is maintained by the packaging system.	Verification: Confirmed by review of Packed Sets (PSs); 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
		Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]

7.2 Electrical and Mechanical Safety

7210						
Defines t	Defines the safety classifications applied from the standard EN 60601-1					
Ref	Specification		Verification/Validation			
7/23	Type of protection against electric shock.	Internally powered equipment	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]			
			Validation: Confirmed by review of Report 087585 on MS26 SN 3112 issued by BSI Testing and the EC Type Examination Certificate No. 1247 for the MS26 issued by BSI. There have been no major changes to the design since these were issued. The MS16A, MS18 and MS 32 are of the same basic construction. The MS32 design is derived from the MS26 in which only the rate range has been internally adjusted. Certificates issued by BSI Testing show the Syringe Drivers meet the requirements of standard IEC 601-1; MS16A Cert. No. 115636/1, MS18 Cert. No. 115637/1 and MS26 Cert. No. 115638/1. [12/3/98 CW]			
7/24	Degree of protection against electric shock.	Type BF Applied Part	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]			
			Validation: As Ref 7/23. [12/3/98 CW]			
7/25	Degree of protection against water ingress.	IPX0	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707, [12/3/98 CW]			
			Validation: Appropriate warnings given in Instruction Manuals; MS16A/MS26 0105-0549, MS18 0112-0031, MS32 0113-0045. [12/3/98 CW]			
7/26	Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with	Not suitable	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]			
	oxygen or nitrous oxide.		Validation: Appropriate warnings given in Instruction Manuals; MS16A/MS26 0105-0549, MS18 0112-0031, MS32 0113-0045. [12/3/98 CW]			
7/27	Mode of operation.	Continuous	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]			
			Validation: As Ref 7/23. [12/3/98 CW]			

lectromagnetic	compatibility		
he level of emission	s of and the immunity to, ele	ctromagnetic radiation.	
	Specification		Verification/Validation
Emissions	EN 60601-1-2	Group 1 Class B	Verification: As Validation. Validation: Confirmed by review of EMC reported in Validation Report VR/105-002. No complaints found in Complaints History Review CHR002/01. [12/3/98 CWI
Immunity	EN 60601-1-2	ESD at 3 kV contact and 8 kV air Radiated RF 26 MHz to 1 GHz at 10 V/m	Verification: As Validation. Validation: Confirmed by review of EMC reported in Validation Report VR/105-002. No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]
lechanical surfa	aces		
he physical conditior	n required for the surfaces o	f the device.	
Specification			Verification/Validation
The Device surfac the skin.	es are free of sharp or rough	n features liable to damage	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW] Validation: Confirmed by visual inspection of examples of production Drivers; MS16A, MS18,
	Electromagnetic he level of emissions Emissions Immunity Mechanical surfa he physical condition The Device surfac the skin.	Electromagnetic compatibility he level of emissions of and the immunity to, ele Specification Emissions EN 60601-1-2 Immunity EN 60601-1-2 Immunity EN 60601-1-2 Mechanical surfaces he physical condition required for the surfaces o Specification The Device surfaces are free of sharp or rough the skin.	Electromagnetic compatibility he level of emissions of and the immunity to, electromagnetic radiation. Specification Emissions EN 60601-1-2 Group 1 Class B Immunity EN 60601-1-2 ESD at 3 kV contact and 8 kV air Radiated RF 26 MHz to 1 GHz at 10 V/m Mechanical surfaces he physical condition required for the surfaces of the device. Specification The Device surfaces are free of sharp or rough features liable to damage the skin.

7.3 Biological

Defines the biological compatibility of the device when used on humans, as intended.

Guidance: Device category - Non-contact device (EN 30993-1:1994). No testing required.

Rei	Specification	Verification/Validation
7/31	The Device does not contain any material unsuitable for the intended purpose.	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
		Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]

7.3.2 Cleanliness

Defines the physical cleanliness required.

Ref	Specification	Verification/Validation
7/32	NOT USED	

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7.4 Environmental

7.4.1	Temperature		
Defines	the permitted temperature	range for the device to be used and stored in	n.
Ref	Ref Specification		Verification/Validation
7/33	Operating	+10 °C to +40 °C	Verification: Conditions not special or abnormal. Specific design output not required. [12/3/98 CW]
·····			Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]
7/34	Storage	-40 °C to +70 °C	Verification: Outer packaging labelling has instruction to keep out of direct sunlight. Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
			Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]
7.4.2 Defines	Humidity the permitted humidity ran	ge for the device to be used and stored in.	
Ref	of Specification		Verification/Validation
7/35	Operating	30 % to 75 % RH	Verification: Conditions not special or abnormal. Specific design output not required. [12/3/98 CW]
		non-condensing	Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]
7/36	Storage	10 % to 100 % RH	Verification: Outer packaging labelling has instruction to keep dry. Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707, [12/3/98 CW]
		non-condensing	Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]
7.4.3 I	Pressure		
Defines	the permitted atmospheric	pressure range for the device to be used an	d stored in.
Ref		Specification	Verification/Validation
7/37	Operating	700 hPa to 1060 hPa	Verification: Conditions not special or abnormal. Specific design output not required. [12/3/98 CW]
			Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]
7/38	Storage	500 hPa to 1060 hPa	Verification: Conditions not special or abnormal. Specific design output not required. [12/3/98 CW]
			Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]

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Ref	Specif	ication	Verification/Validation
7/39	Drivers withstand levels of shock and vibration encountered in normal	EN 60601-1	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
	use.		Validation: Confirmed by review of Report 087585 on MS26 SN 3112 issued by BSI Testing and the EC Type Examination Certificate No. 1247 for the MS26 issued by BSI. There have been no major changes to the design since these were issued. The MS16A, MS18 and MS 32 are of the same basic construction. Certificates issued by BSI Testing show the Syringe Drivers meet the requirements of standard IEC 601-1; MS16A Cert. No. 115636/1, MS18 Cert. No. 115637/1 and MS26 Cert. No. 115638/1. [12/3/98 CW]
7/40	Drop from 1 m onto a hard surface	EN 60601-1	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
			Validation: Confirmed by review of Report 087585 on MS26 SN 3112 issued by BSI Testing and the EC Type Examination Certificate No. 1247 for the MS26 issued by BSI. There have been no major changes to the design since these were issued. The MS16A, MS18 and MS 32 are of the same basic construction. Certificates issued by BSI Testing show the Syringe Drivers meet the requirements of standard IEC 601-1; MS16A Cert. No. 115636/1, MS18 Cert. No. 115637/1 and MS26 Cert. No. 115638/1. [12/3/98 CW]
7.4.5 C	Dperating life		
Defines tl	he duration of use the device will contin	ue to meet the specified p	erformance requirements, when used as intended.
Ref	Specif	ication	Verification/Validation
7/41	Continuous use		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
			Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]
7.4.6 S	ihelf life		
Defines the conditions	he duration the device can be stored wi s.	thout deteriorating and me	eet the specified performance requirements, when stored in the specified storage
~~~~	Specification		Verification

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7/12	NOTHEED	
1144	INOT USED	
	I	and the second second second second

## 8. Construction

8.1 Ge	neral arrangement	
Ref	Specification	Verification/Validation
8/1	<ul> <li>The Driver consists of a small rigid plastic enclosure for the drive motor and control electronics. This enclosure can only be opened with the use of a tool. The battery is contained in a separate compartment within this enclosure accessible to the user without the use of a tool.</li> <li>Provision is made for securing the syringe on top of the enclosure and retaining the syringe barrel and finger grips.</li> <li>The movable linear actuator that pushes the syringe plunger has provision to secure the syringe plunger push-button.</li> <li>The enclosure with a syringe fitted can be further protected with a transparent cover.</li> </ul>	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]         Validation: Confirmed by visual inspection of representative example of production Drivers; MS26 SN 27143. [12/3/98 CW]         Note: MS16A, MS18, MS26 and MS32 have a common enclosure and mechanical layout.

8.2 Di Defines	<b>mensions</b> the physical dimensions of	the assembled device.		
Ref	Specification			Verification/Validation
	Dimension	Value	Tolerance	
8/2	Width of body	166 mm	± 1 mm	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
				Validation: Representative example of production Drivers met specification, MS26 SN 27143. / Equipment used: Digital gauge TVM300 SN 1578. / 21 °C. [12/3/98 CW]
				Note: MS16A, MS18, MS26 and MS32 have a common enclosure and mechanical layout.
8/3	Depth of body	23,0 mm	± 0,5 mm	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
				Validation: Representative example of production Drivers met specification, MS26 SN 27143. / Equipment used: Digital gauge TVM300 SN 1578. / 21 °C. [12/3/98 CW]
8/4	Height of body	53,0 mm	± 0,5 mm	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
				Validation: Representative example of production Drivers met specification, MS26 SN 27143. / Equipment used: Digital gauge TVM300 SN 1578, / 21 °C. [12/3/98 CW]
8/5	Actuator travel	60 mm	minimum	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
				Validation: Representative example of production Drivers met specification, MS26 SN 27143. / Equipment used: Digital vernier calliper (150 mm) Mitutoyo. / 21 °C. [12/3/98 CW]
8/6	Width of cover	180 mm	±1mm	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
				Validation: Example of Cover 0105-0529 met specification. / Equipment used: Digital gauge TVM300 SN 1578. / 21 °C. [12/3/98 CW]
8/7	Depth of cover	36 mm	± 2 mm	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
				Validation: Example of Cover 0105-0529 met specification. / Equipment used: Digital gauge TVM300 SN 1578. / 21 °C. [12/3/98 CW]
8/8	Height of cover	94 mm	± 2 mm	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]

		TVM300 SN 1578. / 21 °C. [12/3/98 CW]
8.3 We Defines t	eight he total weight of the assembled device.	
Ref	Specification	Verification/Validation
8/9	190 g maximum (including the battery)	<ul> <li>Verification: Determined by densities of materials and volumes of components specified. Materials and components have been confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]</li> <li>Validation: Sample of production Drivers met specification, 5/MS16A and 10/MS32 with examples of Duracell MN1604 battery. The MS18 has fewer components and will be lighter and the MS26 will weigh the same as the MS32. / Weight: 183,2 g to 184,7 g. / Equipment used: Weighing balance TE5726. [12/3/98 CW]</li> </ul>
8.4 Co Defines t	mponents he components used in the device.	
Ref	Specification	Verification/Validation
8/10	NOT USED	

8.5 Ma	aterials		
Ref	Specification		Verification/Validation
8/11	Body	Rigid plastic, white, antistatic grade. <i>Typical mechanical properties at</i> +23°C 50% <i>RH:</i> Tensile strength at break = 50 MPa Impact strength (Charpy notched) = 13 kJm ⁻² Hardness (Rockwell) = 100	<ul> <li>Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]</li> <li>Validation: Confirmed by audit of material specifications used in assembly and then review of manufacturer's data. / ABS DSM Ronfalin RTA 50. [12/3/98 CW]</li> </ul>
8/12	Cover	Rigid plastic, transparent, impact resistant. <i>Typical mechanical properties at</i> +23°C 50% <i>RH:</i> Tensile strength at break = 70 MPa Impact strength (Charpy notched) = 35 kJm ⁻² Hardness (Rockwell) = 70	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW] Validation: Confirmed by audit of material specifications used for Cover 0105-0529 and then review of manufacturer's data. / PC GE Plastics Lexan 121. [12/3/98 CW]
8/13	All	No medicinal products (Directive 65/65/EEC)	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]         Validation: Confirmed by audit of component and material specifications used in assembly and then review of manufacturer's data. [12/3/98 CW]
8/14	All	No materials of animal origin	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707.         [12/3/98 CW]         Validation:       Confirmed by audit of component and material specifications used for external parts and then review of manufacturer's data.
8/15	All	No natural latex	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW] Validation: Confirmed by audit of component and material specifications used for external parts and then review of manufacturer's data, [12/3/98 CW]

#### 9. Labelling

Ref	Specification				
				Verification/Validation	
	Information	Format			
9/1	Type identification colour	Blue Silver Green Light grev	MS16A MS18 MS26 MS32	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW] Validation: Awaiting production examples of Drivers with latest labelling.	
9/2	Instructions for use.	Abbreviated instructions. Prominent warning on MS32 to only use with B-D PLASTIPAK 20 mLevringe		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW] Validation: Awaiting production examples of Drivers with latest labelling	
9/3	The Company name.	was b-b FLAS HFAR 20 88 Syllige.		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]	
9/4	The Company postal address.			Validation: Awaiting production examples of Drivers with latest tabelling, Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]	
				Validation: Awaiting production examples of Drivers with latest labelling.	
9/5	The device name.	MS16A Hourly Rate Syringe Driver MS18 Fixed Rate Syringe Driver MS26 Daily Rate Syringe Driver MS32 Volumetric Rate Syringe Driver		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW] Validation: <u>Awaiting production examples of Drivers with latest labelling</u> ,	
9/6	A unique manufacturing serial number.	Symbol from EN 980		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW] Validation: Awaiting production examples of Drivers with latest labelling.	
9/7	The manufacturing year.	Symbol and date format from EN 980		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW] Validation: Awaiting production examples of Drivers with latest labelling.	
9/8	Degree of protection against electric shock.	Symbol from EN 60 Applied Part	601-1 for Type BF	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW] Validation: Awaiting production examples of Drivers with latest labelling.	

or Device labelling	9.1	Device	labelling
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Defines the labelling on the device, either directly marked or on labels.

Ref	Specification			Verification/Validation
	Information	Foi	rmat	
9/9	9/9 Read accompanying instructions Symbol from EN 60601-1/EN 980 for use.		601-1/EN 980	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
				Validation: Awaiting production examples of Drivers with latest labelling.
9/10	The CE mark (with Notified Body number).	As required by Directive 93/42/EEC		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
				Validation: Awaiting production examples of Drivers with latest labelling.
9/11	Battery voltage and type.	attery voltage and type. 9 V, 6LR61		Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW]
				Validation: Awaiting production examples of Drivers with latest labelling.
9/12	Measuring scale.	60 mm linear	MS16A	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001 and 0113-0002. [12/3/98 CW]
		scale, 1 mm graduations	MS18 MS26	Validation: Awaiting production examples of Drivers with latest labelling.
9/13	Start control	START/TEST	MS16A MS18	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707.
			MS32	Volidation: Avoition production examples of Drivers with laterat lateralling
		START/BOOST	MS26	validation. Awaining production examples of Drivers with latest labelling.
9/14	Rate units	mm per 1 h 5 mm per 1 h mm per 24 h mi per 1 h	MS16A MS18 MS26 MS32	Verification: Confirmed by review of GAs; 0105-0501, 0112-0001, 0113-0002 and 0113-0707. [12/3/98 CW] Validation: Awaiting production examples of Drivers with latest labelling.

## 9.2 Packaging labelling

Defines the minimum information appearing on the packaging, either directly printed or on labels.

## KEY: P = Pack, S = Secondary container, T = Tertiary container, ✓ = required, o = optional, - = not used

Ref	Speci	fication	<u>.</u>		·	Verification/Validation
	Information	Format	Р	s	Т	
9/15	The Company name.		~	-	-	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
						Validation: Awaiting production examples of packaged Drivers.
9/16	The Company postal address.		1	-	-	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
						Validation: Awaiting production examples of packaged Drivers.
9/17	The device name.		~	-	~	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
						Validation: Awaiting production examples of packaged Drivers.
9/18	The device item number.	Symbol from EN 980 and Driver reference	1	-	-	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
		number.				Validation: Awaiting production examples of packaged Drivers.
9/19	A unique manufacturing serial	Symbol from EN 980	✓	-	-	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
						Validation: Awaiting production examples of packaged Drivers.
9/20	The CE mark (with Notified Body number).	As required by Directive 93/42/EEC	~	-	-	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
						Validation: Awaiting production examples of packaged Drivers.
9/21	List of contents of packaging.		~	-	-	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
						Validation: Awaiting production examples of packaged Drivers.
9/22	Instruction to store out of direct	Symbol from EN 20780	~	-	-	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
						Validation: Awaiting production examples of packaged Drivers.
9/23	Instruction to keep dry.	Symbol from EN 20780	~	-	-	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
						Validation: Awaiting production examples of packaged Drivers.
9/24	Instruction that contents are fragile.	Symbol from EN 20780	~	-	-	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]

#### 9.2 Packaging labelling

Defines the minimum information appearing on the packaging, either directly printed or on labels.

## KEY: P = Pack, S = Secondary container, T = Tertiary container, $\checkmark$ = required, o = optional, - = not used

Ref	Specif	ication				Verification/Validation
	Information	Format	Р	S	Т	
						Validation: Awaiting production examples of packaged Drivers.

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#### 10. Packaging

10 1 D	ack		
Defines th	ne packaging for the device.		
Ref	Specit	fication	Verification/Validation
10/1	Type/construction	Carton, box with top opening lid and locking tabs, single-wall corrugated fibreboard 125OY/E/125T.	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW] Validation: Awaiting production examples of packaged Drivers.
10/2	Size - internal	222 mm wide x 130 mm deep x 60 mm high ± 2 mm.	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW] Validation: Awaiting production examples of packaged Drivers.
10/3	Contents	1 Driver 1 Instruction manual 1 battery 1 cover 1 carrying holster 1 rate adjusting tool (MS16A, MS26, MS32)	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW] Validation: <u>Awaiting production examples of packaged Drivers</u> .
10/4	Weight (filled)	g ± 2 g	Verification: Determined by densities of materials and volumes of components specified. Materials and components have been confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW] Validation: Awaiting production examples of packaged Drivers.
10/5	Print colour	Blue (Pantone PMS 286).	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW] Validation: Awaiting production examples of packaged Drivers.
10.2 Se	econdary container		
Pof	e packaging for a number of packaged	a devices.	
10/6	NOT USED		vermcation/validation

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10.3 Te	ertiary container		
Dennes tr	ie packaging for final sh	ipment of packaged devices.	
Ref	L	Specification	Verification/Validation
10/7	NOT USED		

#### 11. Documentation

Ref	Specification	Verification/Validation
11/1	Instruction manual intended for user.	Verification: Confirmed by review of PSs; 0105-0504, 0112-0002, 0113-0001 and 0113-0707. [12/3/98 CW]
		Validation: Confirmed by inspection of Instruction Manuals; MS16A/MS26 0105-0549, MS18 0112-0031, MS32 0113-0045. No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]
11/2	Service manual intended for technical personnel involved in maintaining Drivers.	Verification: Confirmed by review of Master Record Indexes; 7T/105-504, 7T/112-002, 7T/113-001 and 2E/113-707. [12/3/98 CW]
		Validation: Confirmed by inspection of Service Manuals SM105/5, SM112, SM113, SM-MS32. No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]

#### 12. Maintenance and Serviceability

Ref	Specification	Verification/Validation
12/1	The Device requires maintenance. Annual performance checks are advised.	Verification: Confirmed by review of Instruction Manuals; MS16A/MS26 0105-0549, MS18 0112-0031, MS32 0113-0045. [12/3/98 CW]
		Validation: No complaints found in Complaints History Review CHR002/01. [12/3/98 CW]

#### 13. Regulatory requirements

#### 13.1 Country/Area

13.1.1	13.1.1 European Community Defines the regulatory requirements for the EC and EFTA member states.					
Defines t						
Ref	Specification	Verification/Validation				
13/1	The Drivers are specified to meet all the relevant requirements of the Medical Device Directive 93/42/EEC of June 1993, as amended. The devices have been classified for the requirements of this directive as: <b>Risk Class IIb</b> (active devices).	Verification: Confirmed by review of Master Record Indexes; 7T/105-504, 7T/112-002, 7T/113-001 and 2E/113-707. And by review of Report 087585 on MS26 SN 3112 issued by BSI Testing and EC Type Examination Certificate No. 1247 for the MS26 issued by BSI. There have been no major changes to the design since these were issued. Certificates issued by BSI Testing show the Syringe Drivers meet the requirements of standard IEC 601-1; MS16A Cert. No. 115636/1, MS18 Cert. No. 115637/1 and MS26 Cert. No. 115638/1. The MS32 design is derived from the MS26 in which only the rate range has been internally adjusted. [12/3/98 CW]				
		Validation: Conformity to all relevant requirements of Directive shown in Essential Requirements Checklist ER002/01. [12/3/98 CW]				

Notes.

1. Key: x = mean value, s = sample standard deviation.

2. All temperatures were in the range 18 °C to 25 °C and were measured or confirmed using digital thermometer TE5597.