



VIA MED

Microstim MkIII

Supramaximal Nerve Stimulator

Class IIa
Via Rule Rule 10
Assesment Route Annex II
NBOG MD 1103

Carried out by Derek Lamb
04 / 12 / 23



VIA MED

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Stock References Review

Stock Reference	Description
2500000	Microstim DB3 - PCB Assembly.
2510000	Microstim DB3 - Supramaximal Nerve
2510001	Microstim DB3 - Supramaximal Nerve
2510005	Microstim DB3 Tester
2520000	Microstim DB3 - Patient Lead.
2520001	Microstim DB3 - Patient Lead.
2520003	Microstim DB3 - Patient Lead.
2520020	Microstim DB3 - Patient Lead.
2520021	Microstim DB3 - Patient Lead.
2530001	Microstim DB3 - Upper Case.
2530002	Microstim DB3 - Lower Case.
2530003	Microstim DB3 - Lower Case Label.
2530004	Microstim DB3 - Battery Cover .
2530005	Microstim DB3 - Battery contact +ve.
2530006	Microstim DB3 - Battery contact -ve.
2530007	Microstim DB3 - Cable Battery Contacts
2530008	Microstim DB3 - Case Screw.
2530009	Microstim DB3 - PCB Assembly Screw.
2530010	Microstim DB3 - Output Connector.
2530011	Microstim DB3 - Mode Switch & Bezel.
2530012	Microstim DB3 - Intensity Control Knob.
2530013	Microstim DB3 - Potentiometer.
2530014	Microstim DB3 - Audio Transducer.
2530015	Microstim DB3 - Transistor PSS8050C
2530016	Microstim DB3 - LED Indicator
2530017	Microstim DB3 - Label
2530018	Microstim DB3 - Voltage Regulator
2530019	Microstim DB3 - Transistor BD237G
2530020	Microstim DB3 - PIC Processor
2530021	Microstim DB3 - PIC Processor
2530023	Microstim DB3 - DIP Socket 18 Contacts
2530024	Microstim DB3 - Crystal 4 MHz.
2530050	Microstim DB3 - Mode Switch.
2530051	Microstim DB3 - Mode Switch Rocker-Green
2530052	Microstim DB3 - Mode Switch Bezel-Black
2530053	Microstim DB3 - PIC Processor
2530054	Microstim DB3 - PIC Processor
2530060	Microstim DB3 - Crocodile Clip - Red
2530061	Microstim DB3 - Crocodile Clip - Black
2530091	Microstim DB3 - Mode Switch & Bezel.
2550001	Microstim DB3 - Electrode.
2550002	Microstim DB3 - Electrodes. Pack of 30.

Stock Reference	Description
2550004	Microstim DB3 - Electrodes. Box of 300.
2590001	Microstim DB3 - Packaging box.
2590002	Microstim DB3 - Packaging insert tray.
2590010	Microstim DB3 - Leaflet.
2590012	Microstim DB3 Product Application Shee
2590014	Microstim DB3 - Technical Manual.
DB37	10K Potentiometer

Comments on Stock references review:

part numbers upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0131352	Oxycal Enclosure	00011450	A9064107	OKW Enclosures	B
DB37	10K Potentiometer	00011963	149-4212-10K	Nobel Electronics Limite	B
2510000	Microstim DB3 - Supramax	00012164		Healthcare Technology In	B
2500000	Microstim DB3 - PCB Asse	00012164	2500000	Healthcare Technology In	B
2520000	Microstim DB3 - Patient	00012164		Healthcare Technology In	B
2530001	Microstim DB3 - Upper Ca	00012164	2530001	Healthcare Technology In	B
2530002	Microstim DB3 - Lower Ca	00012164	2530002	Healthcare Technology In	B
2530004	Microstim DB3 - Battery	00012164	2530004	Healthcare Technology In	B
2530005	Microstim DB3 - Battery	00012164	2530005	Healthcare Technology In	B
2530006	Microstim DB3 - Battery	00012164	2530006	Healthcare Technology In	B
2530007	Microstim DB3 - Cable B	00012164	2530007	Healthcare Technology In	B
2530008	Microstim DB3 - Case Scr	00012164	2530008	Healthcare Technology In	B
2530009	Microstim DB3 - PCB Asse	00012164	03S-68701	Healthcare Technology In	B
2530010	Microstim DB3 - Output C	00012164	2530010	Healthcare Technology In	B
2530011	Microstim DB3 - Mode Swi	00012164	2530011	Healthcare Technology In	B
2530012	Microstim DB3 - Intensit	00012164	2530012	Healthcare Technology In	B
2530014	Microstim DB3 - Audio Tr	00012164	2530014	Healthcare Technology In	B
2590001	Microstim DB3 - Packagin	00012164		Healthcare Technology In	B
2530003	Microstim DB3 - Lower Ca	00012164	2530003	Healthcare Technology In	B
2590002	Microstim DB3 - Packagin	00012164		Healthcare Technology In	B
2590010	Microstim DB3 - Leaflet.	00009360		Print Centre	C
2550004	Microstim DB3 - Electrode	00012034	31.1946.21	Covidien (UK) Commercial	B
2520001	Microstim DB3 - Patient	00012164	14C-98881 REV.A	Healthcare Technology In	B
2530060	Microstim DB3 - Crocodil	00009123	483-843	RS Components Ltd	B
2530061	Microstim DB3 - Crocodil	00009123	483-859	RS Components Ltd	B
2590010	Microstim DB3 - Leaflet.	00009345		Duffield Printers	A
2530013	Microstim DB3 - Potentio	00009061	484-8575P	Farnell	B
2530015	Microstim DB3 - Transist	00009023		Electronics Direct	B
2530013	Microstim DB3 - Potentio	00011963	484-8575P	Nobel Electronics Limite	B
2530052	Microstim DB3 - Mode Swi	00009061	120-1357	Farnell	B
2530053	Microstim DB3 - PIC Proc	00009329		Worldlight Engineering L	B
2550002	Microstim DB3 - Electrode	00009602		Bunzl Healthcare	B
2520003	Microstim DB3 - Patient	00012399		Unimed	C
2520001	Microstim DB3 - Patient	00009132	14C-98881 REV.A	Carlisle Medical Tec (LH	B
2520000	Microstim DB3 - Patient	00009132		Carlisle Medical Tec (LH	B
2500000	Microstim DB3 - PCB Asse	00009166	2500000	Medu-Scientific Ltd	B
2530001	Microstim DB3 - Upper Ca	00009166	2530001	Medu-Scientific Ltd	B
2530002	Microstim DB3 - Lower Ca	00009166	2530002	Medu-Scientific Ltd	B
2530003	Microstim DB3 - Lower Ca	00009166	2530003	Medu-Scientific Ltd	B
2530004	Microstim DB3 - Battery	00009166	2530004	Medu-Scientific Ltd	B
2530005	Microstim DB3 - Battery	00009166	2530005	Medu-Scientific Ltd	B
2530006	Microstim DB3 - Battery	00009166	2530006	Medu-Scientific Ltd	B

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
2530008	Microstim DB3 - Case Scr	00009166	2530008	Medu-Scientific Ltd	B
2530010	Microstim DB3 - Output C	00009166	2530010	Medu-Scientific Ltd	B
2530012	Microstim DB3 - Intensit	00009166	2530012	Medu-Scientific Ltd	B
2530014	Microstim DB3 - Audio Tr	00009166	2530014	Medu-Scientific Ltd	B
2530016	Microstim DB3 - LED Indi	00009166	2530016	Medu-Scientific Ltd	B
2530007	Microstim DB3 - Cable B	00009166	2530007	Medu-Scientific Ltd	B
2530011	Microstim DB3 - Mode Swi	00009166	2530011	Medu-Scientific Ltd	B
2590010	Microstim DB3 - Leaflet.	00009366		Warwick Printing	B
2530013	Microstim DB3 - Potentio	00009123	484-8575P	RS Components Ltd	B
2530024	Microstim DB3 - Crystal	00009123	693-6936	RS Components Ltd	B
2510000	Microstim DB3 - Supramax	00009166		Medu-Scientific Ltd	B
2530023	Microstim DB3 - DIP Sock	00009061	1077319	Farnell	B
2530018	Microstim DB3 - Voltage	00009061	1469108	Farnell	B
2530020	Microstim DB3 - PIC Proc	00009061	9760865	Farnell	B
2530019	Microstim DB3 - Transist	00009061	9557571	Farnell	B
2530017	Microstim DB3 - Label	00010665	2530017	Pendle Signs & Plastics	B
2590010	Microstim DB3 - Leaflet.	00009363		ACI Print Group Impress	B
2550002	Microstim DB3 - Electrode	FL39B01			Needs Grading
2520000	Microstim DB3 - Patient				A

Comments on Suppliers:

suppliers upto date, active supplier reviewed, most no longer required as no longer producing units

Sales Information

Stock Reference	Description	2017	2018	2019	2020	2021	2022	2023
2500000	Microstim DB3 - PCB Asse	1	1		2	2		
2510000	Microstim DB3 - Supramax	398	369	136	1			
2510001	Microstim DB3 - Supramaximal Nerve							
2510005	Microstim DB3 Tester	17	24	10	4	16		1
2520000	Microstim DB3 - Patient	1301	1139	1192	368	312	312	242
2520001	Microstim DB3 - Patient	466	70	231	49	49	13	25
2520003	Microstim DB3 - Patient	197	137	63		17	24	20
2520020	Microstim DB3 - Patient Lead.	2	4	1	1	4		
2520021	Microstim DB3 - Patient Lead.	1						
2530001	Microstim DB3 - Upper Ca	5	5				4	
2530002	Microstim DB3 - Lower Ca	5	5					
2530003	Microstim DB3 - Lower Ca	5		5				
2530004	Microstim DB3 - Battery	28	8	27	13	2	10	
2530005	Microstim DB3 - Battery					3		
2530006	Microstim DB3 - Battery					3		
2530007	Microstim DB3 - Cable B					3		
2530008	Microstim DB3 - Case Scr							
2530009	Microstim DB3 - PCB Asse							
2530010	Microstim DB3 - Output C							
2530011	Microstim DB3 - Mode Swi	7	3	9	2		3	
2530012	Microstim DB3 - Intensit	191	168	200	19	15	17	22
2530013	Microstim DB3 - Potentio	1	2	2	2			
2530014	Microstim DB3 - Audio Tr	5	3	1	2			
2530015	Microstim DB3 - Transist							
2530016	Microstim DB3 - LED Indi							
2530017	Microstim DB3 - Label							
2530018	Microstim DB3 - Voltage							
2530019	Microstim DB3 - Transist							
2530020	Microstim DB3 - PIC Proc							
2530021	Microstim DB3 - PIC Processor							
2530023	Microstim DB3 - DIP Sock							
2530024	Microstim DB3 - Crystal							
2530050	Microstim DB3 - Mode Switch.							
2530051	Microstim DB3 - Mode Switch Rocker-Green							
2530052	Microstim DB3 - Mode Swi							
2530053	Microstim DB3 - PIC Proc							
2530054	Microstim DB3 - PIC Processor							
2530060	Microstim DB3 - Crocodil							
2530061	Microstim DB3 - Crocodil							
2530091	Microstim DB3 - Mode Switch & Bezel.							
2550001	Microstim DB3 - Electrode.							
2550002	Microstim DB3 - Electrode	6						

Stock Reference	Description	2017	2018	2019	2020	2021	2022	2023
2550004	Microstim DB3 - Electrode	1		5				
2590001	Microstim DB3 - Packagin							
2590002	Microstim DB3 - Packagin							
2590010	Microstim DB3 - Leaflet.		50					
2590012	Microstim DB3 Product Application Shee							
2590014	Microstim DB3 - Technical Manual.							
DB37	10K Potentiometer							

Comments on Sales Information:

stop selling few years ago,
spares still being sold, no issues found

Countries Review

Country	2017	2018	2019	2020	2021	2022	2023
Australia	[X]	[X]	[X]	[X]			
BA State of Bahrain							
Belgium	[X]	[X]	[X]	[X]	[X]		
Canada	[X]	[X]					
Cyprus							
Czech Republic		[X]	[X]				
Denmark							
EG Egypt							
Finland	[X]	[X]	[X]				[X]
France							
G Germany							
Germany						[X]	
GR Greece	[X]						
Greece					[X]	[X]	
HK Hong Kong							
Hong Kong							
IN India							
India							
Ireland		[X]	[X]	[X]	[X]		[X]
Israel							
Kenya							
KU Kuwait							
Lebanon							
Malaysia							
Morocco							
Netherlands					[X]		
New Zealand	[X]	[X]	[X]				[X]
Northern Ireland	[X]						
Norway							
OL12 ONB		[X]					
Oman			[X]				
Portugal							
Saudi Arabia		[X]					
Scotland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
South Africa							
Spain							
Switzerland	[X]	[X]	[X]				
Turkey							
UAE							
UK	[X]	[X]	[X]	[X]	[X]	[X]	[X]
UK United Kingdom	[X]	[X]	[X]				
United Kingdom	[X]	[X]	[X]				

Comments on Sales to Countries:

just spares being sold

Comments on Risks with Sales to Countries:

no risks to countries sales

Returns and Q.A. Fails Review

Stock Reference	Fault	2017	2018	2019	2020	2021	2022	2023
2510000	Audio Transducer Replaced							
2510000	Batteries Have Been Changed							
2510000	Batteries Have Leaked							
2510000	Battery Contacts Tightened.							
2510000	Case fault		3		1	3	1	
2510000	Control knob missing		1	1	1	1		
2510000	Control Knob Replaced	1						
2510000	Control Knob Spins	25	39	9		3	3	
2510000	Corrosion		1					1
2510000	Customer Attempted Repair	2						
2510000	D1 Diode failed	1	1					
2510000	Damaged During Transit							
2510000	Dead	1	1					
2510000	Diode Replaced							
2510000	Disassembled By The Customer							
2510000	Does Not Light Up Tester							
2510000	Dry Joint		1					
2510000	End Of Life Demo Unit							
2510000	Failed QA. For Testing And Repair	33						
2510000	False Battery Low Warning							
2510000	Faulty Patient Cable	10	7	2	4			
2510000	Faulty Patient Cable Replaced	1						
2510000	Fluid ingress		1	2				
2510000	Intensity Knob Fitted							
2510000	Intermittent Fault		6	5	6	11	1	1
2510000	Investigate		1			1		
2510000	Leads Replaced							
2510000	LED fault				1			
2510000	LED Replaced							
2510000	Liquid Ingress	3		2				
2510000	Marked		1					
2510000	Mode Switch Fault	1	2	2	2			
2510000	Mode Switch Replaced							
2510000	Modified To PN:2510001							
2510000	Multiple faults			2	5	2	2	2
2510000	New		5				1	
2510000	No Fault Found	4	1	5	3	1	1	
2510000	No Fault Return To Stock							
2510000	No Output	2	4	16	11	9	3	3
2510000	PCB Assembly							
2510000	PCB Assembly Replaced							
2510000	PCB Fault	2	2	1				

Stock Reference	Fault	2017	2018	2019	2020	2021	2022	2023
2510000	QA failed				13			
2510000	Return Stock / Demo Stock							
2510000	ReWorked After QA	1						
2510000	Serviced	2	5					
2510000	Tested OK							
2510000	Timing Crystal Failed	9	2					
2510000	TOF fault			1				
2510000	Unchecked - Returned To Stock	1						
2510005	No Fault Found	2						
2510005	Unchecked - Returned To Stock							
2520000	Needs Evaluating							17
2520000	Cable Intermittent Open Circuit			2				
2520000	Cable Open Circuit						1	
2520000	New			1				
2520000	new stock returned		1					
2520000	No Fault Return To Stock							
2520000	Unchecked - Returned To Stock							
2520003	Unchecked - Returned To Stock							
2530002	Needs Evaluating							
2530004	No Fault Return To Stock							
2530004	Unchecked - Returned To Stock							
2530012	No Fault Return To Stock							
2530012	Physical damage		1					
2530013	No Fault Return To Stock							

Comments on Returns:

limited number of returns,
no issues

Comments on Risks with Returns and Potential Re-work:

no reworks

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes

Comments on Risks with Design Changes:

no design changes

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
121772	Microstim DB3 Instructions for Use User Manual Microstim IFU 20...	19/06/23
121770	Microstim DB3 Instructions for Use / User Manual English	19/06/23
121768	Microstim MkIII Instructions for Use User Manual Microstim IFU ...	19/06/23
121280	Microstim MkIII (Veterinary) Instructions for Use User Manual v1...	13/06/23
121278	Microstim MkIII (Veterinary) Instructions for Use User Manual v1...	13/06/23
121276	Microstim MkIII (Veterinary) Instructions for Use User Manual v1...	13/06/23
121274	Microstim MkIII (Veterinary) Instructions for Use User Manual ...	13/06/23
26449	Microstim MkIII Labels 2510001 Label	14/06/18
17165	Microstim Manual French 2016-07-04 (+5mm bleed)	06/07/16
17164	Microstim MkIII Instructions for Use / User Manual French email	06/07/16
17163	Microstim DB3 Instructions for Use / User Manual French	06/07/16
16863	Microstim MkIII Instructions for Use User Manual 2590102 func...	09/05/16
12210	Microstim MkIII Instructions for Use / User Manual Danish Certif...	29/11/12
12209	Microstim DB3 Instructions for Use / User Manual Danish	29/11/12
1059	Microstim Instructions for Use / User Manual Placement Diagram	31/10/06

Comments on User Instructions:

small typo fixed in ui,
no major changes

Comments on Risks User Instructions:

no risks with changes - typo fix

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
121296	Microstim DB3 (Veterinary) Outer Box Label	13/06/23
121286	Microstim DB3 Veterinary Outer Box Label (Print A4 4pp)	13/06/23
26937	Microstim DB3 Outer Box Label	07/08/18
26457	Microstim MkIII Labels Single Page view	14/06/18
26453	Microstim MkIII Labels 250001 box label	14/06/18
26449	Microstim MkIII Labels 2510001 Label	14/06/18
21702	Microstim MkIII Labels back machine	01/09/17
21700	Microstim MkIII Labels OuterBox Label	01/09/17
9169	No accessory labels	18/10/11
4792	Microstim MkIII Labels	20/10/08
3301	Microstim MkIII Labels	26/02/08

Comments on Labels:

no changes to labels,
units not being produced

Comments on Risks Labels:

Documentation Updates / Changes

Comments on Document Changes:

no changes

Comments on Risks with Document Changes:

Clinical / FDA Incidents online search

Clinical Investigation online review

Comments on Issues:

no problems found in the issue system

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Risks with Issues:

Comments on Clinical Search :

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :