



VIA MED

Heat Shields

Simple tunnel to restrict heat loss. Available with and without feet ends.

Class I
Via Rule Rule 1
Assesment Route Annex II
NBOG MD 0100

Carried out by Derek Lamb
25 / 10 / 18



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
-  User Instructions Review
-  Labels Review
-  Document Updates Review
-  Internal Issues Review
-  Clinical / FDA Incidents online search

Stock References Review

Stock Reference	Description
PP8100	Heat Shield Open Ends
PP8101	Heat Shield one end open
PP8102	Heat Shield Both Ends Closed
PP8103	Heat Shield Open Ends
PP8104	Heat Shield One End Closed
PP8105	Heat Shield Both Ends Closed
PP8106	Heat Shield Open Ends
PP8107	Heat Shield Open One End
PP8108	Heat Shield Both Ends Closed
PP8109	Heat Shield Open Ends
PP8110	Heat Shield One End Closed
PP8111	Heat Shield Both Ends Closed
PP8112	Heat Shield Open Ends
PP8113	Heat Shield One End Closed
PP8114	Heat Shield Both Ends Closed
PP8601	Heat Shield Open Ends
PP8620	Heat Shield One End Closed
PP8633	Heat Shield
PP8761	Heat Shield Both Ends Open
PP8779	Heat Shield Open Ends
PP8786	Heat Shield

Comments on Stock references review:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
PP8109	Heat Shield Open Ends	00009022	PP8109	Tanda Engineering Ltd	B
PP8112	Heat Shield Open Ends	00009022	PP8112	Tanda Engineering Ltd	B
PP8633	Heat Shield	00009022	PP8633	Tanda Engineering Ltd	B
PP8761	Heat Shield Both Ends O	00009022	PP8761	Tanda Engineering Ltd	B
PP8779	Heat Shield Open Ends	00009022	PP8779	Tanda Engineering Ltd	B
PP8786	Heat Shield	00009022	PP8786	Tanda Engineering Ltd	B

Comments on Suppliers:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Sales Information

Stock Reference	Description	2012	2013	2014	2015	2016	2017	2018
PP8100	Heat Shield Open Ends							
PP8101	Heat Shield one end open							
PP8102	Heat Shield Both Ends Closed							
PP8103	Heat Shield Open Ends							
PP8104	Heat Shield One End Closed							
PP8105	Heat Shield Both Ends Closed							
PP8106	Heat Shield Open Ends							
PP8107	Heat Shield Open One End							
PP8108	Heat Shield Both Ends Closed							
PP8109	Heat Shield Open Ends							
PP8110	Heat Shield One End Closed							
PP8111	Heat Shield Both Ends Closed							
PP8112	Heat Shield Open Ends						1	
PP8113	Heat Shield One End Closed							
PP8114	Heat Shield Both Ends Closed							
PP8601	Heat Shield Open Ends							
PP8620	Heat Shield One End Closed							
PP8633	Heat Shield							
PP8761	Heat Shield Both Ends O	7	2					
PP8779	Heat Shield Open Ends	2						
PP8786	Heat Shield			1				

Comments on Sales Information:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Countries Review

Country	2012	2013	2014	2015	2016	2017	2018
UK United Kingdom	[X]	[X]	[X]			[X]	

Comments on Sales to Countries:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Comments on Returns:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks with Design Changes:

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
7688	Heat Shields Instructions for Use User Manual	15/02/11

Comments on User Instructions:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks User Instructions:

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
16792	Head Box Oxygen Hoods Labels	20/04/16
9169	No accessory labels	18/10/11

Comments on Labels:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
22389	Heat Shields Clinical Trials Reports Reviews and Post Market Sur...	02/10/17

Comments on Document Changes:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks with Document Changes:

Clinical / FDA Incidents online search

Clinical Investigation online review

Comments on Issues:

we have ceased selling these devices due to MHRA / BSI regulations and costs

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

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

we have ceased selling these devices due to MHRA / BSI regulations and costs

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 :

we have ceased selling these devices due to MHRA / BSI regulations and costs