



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
18 / 08 / 16



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
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-  Internal Issues Review
-  Clinical / FDA Incidents online search
-  Risk ISO 14971 : 2012 Review

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:

stock references up to date

Supplier Review

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

Comments on Suppliers:

supplier review up to date

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
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 O			7	2			
PP8779	Heat Shield Open Ends			2				
PP8786	Heat Shield					1		

Comments on Sales Information:

No units being sold

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
UK United Kingdom			[X]	[X]	[X]		

Comments on Sales to Countries:

No units being sold

Comments on Risks with Sales to Countries:

No units being sold

Returns Review

Comments on Returns:

No units being sold

Comments on Risks with Returns and Potential Re-work:

No units being sold

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no changes

Comments on Risks with Design Changes:

n/a

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:

no changes to the ifu

Comments on Risks User Instructions:

n/a

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:

handle with care label designed for the outer box

Comments on Risks Labels:

no risks with new labels

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
16792	Head Box Oxygen Hoods Labels	20/04/16
15617	Heat Shields Packaging Trials and validation 2015 Returned	09/09/15
15616	Heat Shields Packaging Trials and validation 2015 Shipping Out	09/09/15
15615	Heat Shields Packaging Trials and validation 2015 Packaging	09/09/15
15614	Heat Shields Packaging Trials and validation 2015	09/09/15
15424	Heat Shields Risk analysis reports	11/08/15
15418	PPE Equipment	11/08/15
15293	Declaration of Conformity Blank Class I	29/07/15
15183	No risks disposal	21/07/15
15115	Heat Shields Clinical Trials Reports Reviews and Post Market Sur...	25/06/15

Comments on Document Changes:

packaging trials and tests performed.

Comments on Risks with Document Changes:

no risks identified with new documentation

Internal Issues Review

Number of Issues reviewed: 0

Comments on Issues:

No issues, due to no sales

Comments on Risks with Issues:

n/a

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

difficult to find any thing relevant, heat shields is a generic terms.
but nothing found on the internet.

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 :

no FDA reports found