

## Rolling Task:48 Regulatory Requirements

System Generated Ensure all Regulatory requirements are up to date, Check those that relate to the MDr for our discontinued products that are still with in their lifespans. Complete the Document up to date reviews on all documents. European Commission harmonised standards to check documentation upto date [http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm)  
Processid 7978 : Regulatory Requirements

### KEY

Done and Completed

Completed by users waiting closure

Outstanding

Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">240072</a>	27 Oct 2021	Derek Lamb	27 Oct 2021	Derek Lamb	29 Oct 2021	1	2	3

System Generated

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Complete the Document upto date reviews on all documents.

European Commission harmonised standards to check documentation upto date

[http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm)

### **27 Oct 2021 Derek Lamb**

Not sure how this is going to work in fuuture with brexit, however, Our only Standrds currently ISO9001:2015 and ISO13485:2016 are upto date. as we do not have an CE certified medical products we do no have to review our standards library

Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">202133</a>	27 Oct 2020	Derek Lamb		Derek Lamb, Helen Lamb,	02 Feb 2021	-	-	99

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**27 Oct 2020 Derek Lamb**

MDR for distributors needs a little work for ISO13485,

Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">157458</a>	28 Oct 2019	Derek Lamb	28 Oct 2019	Derek Lamb	31 Oct 2019	1	3	4

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**28 Oct 2019 Derek Lamb**

We no longer manufacturer of any medical devices

Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">131050</a>	29 Oct 2018	Derek Lamb	29 Oct 2018	Derek Lamb	01 Nov 2018	1	4	5

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**29 Oct 2018 Derek Lamb**

MDR

Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">106586</a>	27 Oct 2017	John Lamb	09 Apr 2018	Derek Lamb	16 Apr 2018	165	7	172

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**27 Oct 2017 Derek Lamb**

Next Action Changed From Derek Lamb To John Lamb Hi john, intrastats ISO standards REview lists the standards we have in the document index, need to see if we need to update any, and or which we dont require atm so i can take of the active list of standards EN ISO 14971:2007 - European Commission ? we have 2012 copy to use as a guideline?

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**09 Apr 2018 John Lamb**

Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">82310</a>	27 Oct 2016	Derek Lamb		Derek Lamb, Helen Lamb,	14 Feb 2017	-	-	111

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Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">64035</a>	27 Oct 2015	Derek Lamb		Derek Lamb, Helen Lamb,	14 Feb 2017	-	-	477

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Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">53566</a>	27 Oct 2014	Derek Lamb		Derek Lamb,	31 Oct 2014	-	-	5

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Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">46583</a>	28 Oct 2013	Derek Lamb	05 Feb 2014	Derek Lamb, Helen Lamb,	23 Apr 2014	101	77	178

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**05 Feb 2014 Derek Lamb**

was done, updated a few bsi iso documents

Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">39748</a>	29 Oct 2012	Derek Lamb		Derek Lamb, Helen Lamb,	04 Jun 2013	-	-	219

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**04 Jun 2013 Derek Lamb**

Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">31759</a>	28 Oct 2011	Derek Lamb		Derek Lamb,	27 Feb 2012	-	-	123

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## 23 Nov 2011 Derek Lamb

Issue	Date Created	Issue To	Date Completed	Closed By	Date Closed	Days Investigate	Days complete	Overall Days
<a href="#">25571</a>	28 Oct 2010	Derek Lamb		Derek Lamb, Helen Lamb,	14 Mar 2011	-	-	138

System Generated

Ensure all Regulatory requirements are upto date,

including the BSI EN documents are upto date.

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## 18 Jan 2011 Derek Lamb

the attached file was made via openoffice and a link to intrastats,  
the source file is in t:\deek lamb\doc\all\_docs

suggest I generate the file into a img file and make a Auto DOC generator in intrastats and attach to  
each stock menu,