Index of Documentation.

Section.	Description.	Ref MDD / Ref ISO 9001.	Document.	A or NA.	Done.
i	Prelim		Introduction CD amendment controls	A	√
A	Location of documents		Index of documentation Location of documents.	A	√
B	Certifications.	Ann II, V, VI	Declaration of conformity	A	
			Notified body	A	√
			BS EN ISO 9001:1994	A	√
C	Essential requirements	Art 3 / Ann 1	Essential requirements	A	√
	EN standards	Ann II para 3.2c	EN standards	A	√
D	Classification.	Ann IX	Classification rationale	A	√
			MDD flow charts : Non invasive, Invasive, Active, Special rules.	A	√
			EMC rational	A	√
E	Risk Management	Ann I para 1, 2 & 6 Ann II para 3.2c	Risk analysis Class IIa	A	√
			Risk policy & definitions	A	√
			Risk Analysis Report	A	√
			EN ISO 14971: 2001 Ann A	A	√
			EN ISO 14971: 2001 Ann D	A	√
F	Device description etc. Product manuals & labels	Ann II para 3.1	Description device etc.	A	√
		Ann II para 3.1	Accessories	A	√
		Ann I para 13	Labels	A	√
		Ann I para 13	Instructions for use	A	√
			Maintenance manual	A	√
G	Product life	Para 4.5	Product life	A	√
	Product changes	Ann II, V, VI para 3.4	Product changes Proposed product changes	A	√
HI	Post market surveillance	Ann II, V, VI para 3.1	User feedback & complaints	A	√
JK	Production plan / procedures / responsibilities	Ann II para 3.1	Location of responsibilities	A	√
			Manufacturing route	A	√
		Ann II para 3.2c	Work instructions and tests	A	√
		Ann II para 3.2c	Sub assemblies & circuit diagrams	NA	NA
L	Literature reviews		Nascor IGLOO system	A	√
M	Packaging trials and validation		Packaging	A	√
N	Quality plan	Ann II para 3.2	Quality plan	A	√
O	Sterilisation	Ann II para 3.2d	Sterilisation	A	√
PQ	MCA Licenses		MCA Licenses	NA	NA
R	510k			NA	NA
S	Photographs			A	√
T	Specifications of materials		Specifications of Materials	A	√
UV	Purchase specifications			A	√
WX	Parts lists			A	√

YZ	Design Files :				
01	Device History & Theory			A	No
02	Specification Brief			A	No
03	Confidentiality Agreements			A	No
04	Not Used			---	---
05	Time Scale			A	No
06	Not Used			---	---
07	Project Progress			A	No
08	Work logs			A	No
09	Expenditure			A	No
10	Not Used			---	---
11	Risk assessment			A	√
12	Preliminary drawings			A	√
13	Final Drawings			A	√
14	Working Drawings			A	√
15	Not Used			---	---
16	Design Changes			A	√
17	Validation			A	√
18	Quotations			A	√
19	Source codes			A	√
20	Design reviews			A	√
21	Purchases			A	No
22	Test reports	Ann II para 3.2		A	No
23	Not Used			---	---
24	Final inspection & test			A	No
25	Type examinations	Ann V, VI		A	No
26	EMC tests & results			A	No
27	Clinical Trial Reports	Art 15, Annex X		A	√
28	Biocompatiblity	Ann II para 3.2c		A	√
29	Compatibility Trials			A	√
30	Final costings			A	No
31	Not Used			---	---