Type of document / Tipo di documento / Type de document ***Technical Note***			
Project Syndeli RF V2 DF4	*Department:* COE-IDS	*Original stored in:* ***Clamart***	*Department Internal Ref:*

Title: **SYNDELI RF V2 DF4: CHANGES VALIDATION VERSUS PARADYM RF JPN RDY**	*Filed in Intraprod on :* *By:*

Abstract: This document lists the tests already performed on PARADYM RF JPN RDY and evaluates if their results are eligible or not for SYNDELI RF V2 DF4. If needed, some additional tests will be made to finalize the qualification.

Distribution of this document is limited to the following individuals (if not applicable left empty):

	Name	Function	Signature	Date
Prepared by	E. Abhamon	R&D Project leader		June 10th, 2013
Verified by	C. de Jeso	QA CT member		
Verified by	G. Salaün	RA CT member		
Approved by	P. Barou	CT Leader		

HISTORY / STORIA / HISTORIQUE

Rev.	Change	Reason for Change	Release date
A	Original document in English	New project SYRF V2 with DF4 headers	Dec. 5th, 2012
B	- Editorial correction of reference of document SYNDELI RF V2 DF4 Inductive telemetry performances - New revision of PLAN0694D and REP0776D - Removed rev. D of MISC0513	- Previously wrongly referenced MISC1633 instead of MISC1663 - Versioning update - SAR evaluation is fully covered by MISC1665A	

TABLE OF CONTENT / INDICE / TABLE DES MATIERES

1 Scope

This document lists, based on design changes (DF4 new headers), the complete Syndeli RF V2 DF4 V&V that has to be done according to the following three kind of methods :

- Redo tests already performed for PARADYM RF JPN RDY V&V,
- Apply PARADYM RF JPN RDY exisiting plans & reports with justifications,
- Perform new tests not required for PARADYM RF JPN RDY platform and PARADYM RF existing DHF basis.

2 Documents of precedence

Design Verifications & Validations definitions have been defined through the assessment phases concluded by the following top level Syndeli RF V2 Specifications Review & new parts Design Reviews:

- REQ0964 Paradym RF, Paradym V2 & Tri-V, Syndeli RF V2 - Functional Specifications
- REQ0947 Syndeli RF & Syndeli RF V2 DF4 models and ZL modules serial number encoding
- CR00245 DF4 Headers Design Review meeting minutes
- CR00304 Syndeli RF V2 DF4 Specification Review meeting minutes
- MISC1134 Syndeli RF JPN RDY : Changes validation versus Syndeli RF

3 Design changes, Background

3.1 Mechanics

The table below describes all the design changes introduced on those header parts potentially inducing electronics or system performances impacts:

Headers	Change	Reason for change
DF4 headers Vs DF1 headers	Moved to 1 DF-4 cavity from previous 2 DF-1 cavities & 1 IS-1 cavity	Respond to market new standard needs
	3D shape RF antennas vs. Flat RF antenna	DF4 cavity bigger diameter do not allow the integration of the RF antenna in the center plan of the header
	2 different RF antennas: - a large one for CRT-D SonR, CRT-D & DR - a small one for VR	Downsized for VR header
	Main feed-through wires new routing inside the header and contact blocks relocation	DF4 cavity contact blocks location in the DF4 header is not the same as in current DF1 headers

3.2 Electronics

Syndeli RF V2 DF4 products are fully based on Paradym RF JPN ready electronic platform.

3.3 Embedded Software

Syndeli RF V2 DF4 range of devices embeds the same software as Paradym RF JPN Ready, W3.120.1.

4 Syndeli RF V2 DF4 devices identification versus Paradym RF JPN Rdy ones

There's no featuring difference between PARADYM RF JPN RDY and Syndeli RF V2 DF4 one, therefore the same codification of LV hybrid will be used.

Finally we have the following codification & parts constitution:

Project range	Model	Generic Code	Device Code
Syndeli RF V2 DF4	CRT-D SonR	Y6	AD
	CRT-D		AE
	DR		AF
	VR		AG

5 Device definition mapping

Family	Model	Electronic platform		Software	Connector	
		Common parts	Differences		Shape	Cavities
PARADYM RF JPN RDY	VR	- TWAV4C & MOSAIC RF2 chipset - "Y6" Low voltage hybrid with RF lead frame option - SMD components on Low Voltage hybrid and main flex - Shock7 V2 - RF module ZL70102 - Battery - HV capacitors	None	W3.120.1	- One header shape for all models with insulated RF antenna	3 cavities: 1 IS-1 and 2 DF-1
	DR					4 cavities: 2 IS-1 and 2 DF-1
	CRT-D					5 cavities: 3 IS-1 and 2 DF-1
	CRT-D SonR					5 cavities: 3 IS-1 and 2 DF-1 Third cavity IS-1 with additional contact in atrial cavity SonR
Syndeli RF V2 – DF-4	VR				- Two headers shapes: * 1 header for SonR, CRT-D & DR models * 1 low profile header for VR model	1 cavity: 1 DF-4
	DR					2 cavities: 1 IS-1 and 1 DF-4
	CRT-D					3 cavities: 2 IS-1 and 1 DF-4
	CRT-D SonR					3 cavities: 2 IS-1 and 1 DF-4 Second cavity IS-1 with additional contact in atrial cavity SonR

6 Device under test selection

The tests have to be performed on Syndeli RF V2 DF4 CRT-D SonR model because:

- this is the most complete model in terms of functionalities and quantity of contact blocks
- VR DF4 cavity location & design is fully the same as CRT-D SonR one

and consequently covers all range of the Syndeli RF V2 DF4 families. Therefore validation reports will be applicable on all Syndeli RF V2 DF4 models.

7 Syndeli RF V2 DF4 V&V versus Paradym RF JPN Rdy V&V source

The table below describes, based on PARADYM RF JPN Rdy V&V plans and reports and the SYNDELI RF V2 DF4 design changes, all the tests to be either added or redo and those which have been already performed and consequently for which the results are applicable to SYNDELI RF V2 by rationales based on designs comparison (new DF4 connector block vs. DF1 one).

Step	Test Source	Test description	PARADYM RF JPN RDY qualification reports eligible for Syndeli RF V2 DF4 ?	
			Status	Justification
1	PLAN699C	This protocol is intended to qualify the use of CC7 crystal with the oscillator on the Low Voltage hybrid in PARADYM RF JPN RDY	Yes	Same Y6 Hybrid
	REP0783C	This document bears the whole qualification results of the new CC7 crystal oscillator of PARADYM RF JPN RDY		
2	PLAN0700B	- These protocols are intended to validate the G Chain on the Low Voltage hybrid RF in PARADYM RF JPN RDY	Yes	Same Y6 Hybrid
	REP0784B	This document bears the whole qualification results of the G Chain of PARADYM RF JPN RDY		
3	PLAN0841B	-This protocol is intended to verify the non regression of Low Voltage hybrid Y6 compared to Low Voltage hybrid Y3 using in PARADYM JPN RDY	Yes	Same Y6 Hybrid
	REP1061B	This document bears the whole qualification results of the no regression test on Low Voltage hybrid.		
4	PLAN1252A PLAN0758C PLAN0841A	-This protocol is intended to validate the modification of MOSAIC RF V2 compared to MOSAIC RF V2 using in the Low Voltage hybrid RF - This protocol is intended to validate the modification of MOSAIC RF compared to MOSAIC V2B -This protocol is intended to validate the non regression of MOSAIC RF compared to MOSAIC V2B using in the Low Voltage hybrid Y4 and RF	Yes	Same Y6 Hybrid including MV sensor validation
	REP0891B REP1061B REP1932A	These documents bear the whole qualification results of the IC MOSAIC RF & MOSAIC RF V2		

Step	Test Source	Test description	PARADYM RF JPN RDY qualification reports eligible for Syndeli RF V2 DF4 ?	
			Status	Justification
5	PLAN1252A PLAN0698B PLAN0759B PLAN0841B	-This protocol is intended to validate the modification of TWINACE V4C compared to TWINACE V4B using in the Low Voltage hybrid RF -This protocol is intended to validate the modification of TWINACE V4B compared to TWINACE V3B using in the Low Voltage hybrid RF -This protocol is intended to validate the modification of TWINACE V3B compared to TWINACE V2 using in the Low Voltage hybrid Y4 and RF -This protocol is intended to validate the non regression tests of TWINACE V3B compared to TWINACE V2 using in the Low Voltage hybrid Y4 and RF	Yes	Same Y6 Hybrid including MV sensor validation
	REP0892B REP1140B REP1061B REP1932A	These documents bear the whole qualification results of the Integrated Circuit TWINACE V4C TWINACE V4B and TWINACE V3B		
6	PLAN0703B	This protocol is intended to validate the sensing chain in the main FLEX or finished product PARADYM RF JPN RDY	No	Same Main flex assembly
	REP0787B	This document bears the whole qualification results of the Sensing chain of PARADYM RF JPN RDY.		
7	PLAN0705B	This protocol is intended to validate the Inductive telemetry performances on finished product PARADYM RF JPN RDY.	Yes, partially	Same device design as JPN RDY, but influence of DF4 header to be evaluated for Inductive communication performance standpoint
	REP0789B	This document bears the whole qualification results of the inductive telemetry performances of PARADYM RF JPN RDY.		
8	PLAN0695B	This protocol is intended to verify immunity of the final device against EMI emissions and internal or external perturbations to show compliance with EN 45502-2-1: 2003 and EN 45502-2-2: 2008 applicable to the Implantable Cardioverter Defibrillator	Yes, partially	Same device design as JPN RDY, but influence of DF4 lead bore to be evaluated for EMI standpoint (§27.4 & 27.5)
	REP0777B	This document bears the whole qualification results of the standard EN 45502-2-2: 2008 sections {16.2, 16.4, 16.5, 17.1, 19.2, 19.5, 20.2, 21.2, 22.1, 27.2, 27.3, 27.4, 27.5, 27.6, 27.7 and 27.8} of PARADYM RF JPN RDY.		

Step	Test Source	Test description	PARADYM RF JPN RDY qualification reports eligible for Syndeli RF V2 DF4 ?	
			Status	Justification
9	PLAN0694D	This protocol is intended to measure the characteristics on final device according to standards EN 45502-2-1: 2003 and EN 45502-2-2: 2008	Yes, partially	Same device design as JPN RDY, but influence of new header to be evaluated for sensing, EMI, pacing & shock characteristics standpoint (PC69, §6.1.1. & 6.1.4). Atrial ATP characteristics to be evaluated Other previous tests results related to timing are still eligible.
	REP0776D	This document bears the whole qualification results of the standards EN 45502-2-1: 2003 (see sections 10.1 to 10.14 for tests of §6.1.1 to 6.1.9 of the standard) and EN 45502-2-2: 2008 (see sections 10.16 to 10.19 for tests of §6.1.2 to 6.1.6 of the standard) and PARADYM RF JPN RDY.		
10	PLAN0696B	This protocol is intended to describe the tests to be carried out on the device to show compliance with standard AAMI:PC69:2007		
	REP0778C	This document bears the whole qualification results of the safety test of STANDARD AAMI:PC69:2007 of PARADYM RF		
11	PLAN0704A	This protocol is intended to qualify PARADYM RF JPN RDY ICD immunity and functionality against internal RF emissions and perturbations	Yes	Same device design as JPN RDY (electronics and feeds-though)
	REP0788A	This document bears the whole qualification results of ICD immunity and functionality against internal Radio-Frequency (RF) emissions and perturbations of PARADYM RF JPN RDY.		
12	REP2101B MISC0513C	These reports bear the whole of RF ZL70102 feature results with respect to STDs for PARADYM RF JPN RDY models (EC, US & JPN compliance) VR, EMC LCIE report DR, EMC LCIE report CRT, EMC LCIE report SonR EMC LCIE report VR, RADIO LCIE report DR, RADIO LCIE report CRT, RADIO LCIE report SonR, RADIO LCIE report All models, EMF (Human exposure) report SAR simulation report	Yes, partially	Same Electronics & Mechanics as Paradym RF JPN RDY for the DF1 version but DF4 header impact has to be evaluated for radiated power & cells damages

Step	Test Source	Test description	PARADYM RF JPN RDY qualification reports eligible for Syndeli RF V2 DF4 ?	
			Status	Justification
13	PLAN0676B	This document bears the whole of tests performed for validating the assembly technology reliability of the "Y6" main flex assembly encompassing all the electronics (dice & SMD) except the RF module.	Yes	Same Y6 main flex assembly.
	REP1290B	This document bears the whole of tests results for validating the assembly technology reliability of the "Y6" main flex assembly encompassing all the electronics (dice & SMD) except the RF module.		
14	PLAN0678A	This document bears the whole of tests performed for validating the assembly technology reliability of the RF ZL70101 flex assembly encompassing all the electronics (dice & SMD).	Yes	ZL70102 new module do not require any further qualification at RF flex assembly level because no Sorin assembly process change has been introduced, see MISC1134
	REP0745A	This document bears the whole of tests results for validating the assembly technology reliability of the RF ZL70101 flex assembly encompassing all the electronics (dice & SMD).		
15	PLAN1253A	This protocol is intended to qualify the ICD, ZL70102 inside RF communication performances with Smart View Quick-fix Home Monitor (shielded version)	Yes	Same RF ZL70102 module
	REP1933A	This document bears the whole qualification results of the ICD ZL70102 inside RF communication performances		
16	PLAN1261B	This document bears the whole of tests performed for validating the assembly technology reliability of the RF ZL70102 module	Yes	Same RF ZL70102 module
	REP1961A	This document bears the whole of tests results for validating the assembly technology reliability of the RF ZL70102 module		
17	REP2100A	These documents bear the whole qualification tests & results performed by the LCIE certified lab. for insuring ICD & CRT compliance with respect to EN45502 & AAMI/PC69 series STDs.	No	Same Y6 Hybrid, but for mechanics, new DF4 headers: contact blocks location & main FT wires new routing in the header
18	PLAN1105A	This protocol bears the whole of qualification tests for validating the PARADYM RF JPN RDY devices ESW W3.120.1	Yes	Same ESW3.120.1
	REP1949A	This report bears the whole of qualification tests results for validating the PARADYM RF JPN RDY devices ESW W3.120.1		
19	PROTER1N	This document bears the tests protocols to be performed internally and by the LCIE certified lab. for insuring ICD & CRT compliance with respect to EN45502 series	Yes, partially	- Same Y6 Hybrid & Mechanics as Paradym RF JPN RDY except the new DF4 header
	REP1156A	These documents bear the results of the whole qualification tests performed internally and by the LCIE certified lab. for insuring ICD & CRT compliance with respect to EN45502 series		

Step	Test Source	Test description	PARADYM RF JPN RDY qualification reports eligible for Syndeli RF V2 DF4 ?	
			Status	Justification
20	PROTER4J	This document bears the tests protocol to be performed to ensure ICD & CRT compliance with respect to IS-1 and DF-1 standards	No	same electronics and mechanics as Paradym RF JPN RDY but new header with IS-1 cavities and DF4 cavity impact has to be evaluated
	REP1155A	These documents bear the whole qualification tests & results performed to ensure ICD & CRT compliance with respect to IS-1 and DF-1 standards		
21	MISC0482A	This document bears the protocols of tests to be performed to assess the biological effects of the PARADYM RF following the requirements of ISO 10993: Biological Evaluation of Medical Devices, as well as the tests results demonstrating ICD & CRT compliance to this standard.	No	new DF4 header impact has to be evaluated
22	PLAN0950A	This document bears the protocols of tests to be performed to validate the Ethylene Oxide Sterilization BC1 cycle	No	new DF4 header impact has to be evaluated
	REP1308B	This document bears the tests results of the Ethylene Oxide Sterilization BC1 cycle validation		
24	PROTER16D	This process validation protocol defines the tests and associated acceptance criteria to comply with requirements relative to the validation of the sterile packaging sealing process used for sterile barrier systems in accordance with ISO 11607-2:2006, ISO 11607-1:2006 standards and a GHTF guidance	Yes	Same external blister
	REP1167D	This document bears the tests results details the test-results regarding the sterile barrier system sealing		

8 Syndeli RF V2 DF4 V&V, DHF References mapping

The table below describes all the V&V that have to be redone for validating all Syndeli RF V2 DF4 devices range. It's, based on existing PARADYM RF JPN RDY, and DF4 headers design impact on devices performances (refer to the DF4 Design Review meeting minutes CR00245A, slide V&V). For all remaining SYNDELI RF V2 DF4 Mechanics, Electronics & Process V&V (common design & risk management) refer to PARADYM RF JPN RDY existing DHF.

Step	PARADYM RF JPN RDY source		Syndeli RF V2 DF4 V&V GENERAL PLAN	
	DHF Source	Test description	DHF Ref	Test description
1	PLAN0705B	This protocol is intended to validate the Inductive telemetry performances on finished product PARADYM RF JPN RDY.	MISC1663A + PLAN705B as precedence	This document bears the whole qualification results of the inductive telemetry performances of Syndeli RF V2 DF4 for what regards the following test: - EPS cone area versus Paradym RF DF1 one Others PARADYM RF JPN RDY test results are eligible
	REP0789B	This document bears the whole qualification results of the inductive telemetry performances of PARADYM RF JPN RDY	MISC1663A + REP0789B as precedence	
2	PLAN0695B	This protocol is intended to verify immunity of the final device against EMI emissions and internal or external perturbations to show compliance with EN 45502-2-1: 2003 and EN 45502-2-2: 2008 applicable to the Implantable Cardioverter Defibrillator	PLAN1554A + PLAN0695B as precedence	This document bears the whole qualification results of the standard EN 45502-2-2: 2008 sections performed on Syndeli RF V2 DF4 for what regards: - EMI compatibility (§27.4, 27.5) - CMRR Others PARADYM RF JPN RDY test results are eligible
	REP0777B	This document bears the whole qualification results of the standard EN 45502-2-2: 2008 sections {16.2, 16.4, 16.5, 17.1, 19.2, 19.5, 20.2, 21.2, 22.1, 27.2, 27.3, 27.4, 27.5, 27.6, 27.7 and 27.8} of PARADYM RF JPN RDY.	REP2499A + REP0777B as precedence	
3	PLAN0694D	This protocol is intended to measure the characteristics on final device according to standards EN 45502-2-1: 2003 and EN 45502-2-2: 2008	PLAN1555A + PLAN0694D as precedence	This document bears the whole qualification results of the standards EN 45502-2-1: 2003 and EN 45502-2-2: 2008 performed on Syndeli RF V2 DF4 for what regards the following tests: - RV & A Sensing - LV, RV, A Pacing - Shock - RV & A ATP Others PARADYM RF JPN RDY test results are eligible
	REP0776D	This document bears the whole qualification results of the standards EN 45502-2-1: 2003 (see sections 10.1 to 10.14 for tests of §6.1.1 to 6.1.9 of the standard) and EN 45502-2-2: 2008 (see sections 10.16 to 10.19 for tests of §6.1.2 to 6.1.6 of the standard) and PARADYM RF JPN RDY.	REP2500A + REP0776D as precedence	

Step	PARADYM RF JPN RDY source		Syndeli RF V2 DF4 V&V GENERAL PLAN	
	DHF Source	Test description	DHF Ref	Test description
4	PLAN696B	This protocol is intended to describe the tests to be carried out on the device to show compliance with standard AAMI:PC69:2007	PLAN1556A	This document bears the whole qualification results of the safety test of Standard AAMI PC69:2007 of Syndeli RF V2 DF4 for all tests.
	REP778C	This document bears the whole qualification results of the safety test of STANDARD AAMI:PC69:2007 of PARADYM RF	REP2501A	
5	PLAN1253A	This protocol is intended to qualify the RF system communication performances comprising both IMD & Smartview monitor	PLAN1253A as precedence + MISC1239A	The protocol is intended to qualify the RF system communication performances comprising both IMD & Smartview monitor, and the technical note describes the whole qualification strategy of the RF system communication of Syndeli RF V2 DF4 (high & low profile header) devices through design assessment (simulation and characterization) for what regards the effective communication distance range
	REP1933A	This document bears the whole qualification results of ICD RF system communication performance during operation with the Smartview Monitor.	REP1933A as precedence + MISC1239A	The technical note bears the whole design validation tests performed on Syndeli RF V2 DF4 (high & low profile header) for what regards the following test : - ISM & MICS band distance range versus Paradym RF JPN RDY DF1 ones Others PARADYM RF JPN RDY test results are eligible
6	REP2101B MISC0513C	These reports bear the whole of RF ZL70102 feature results with respect to STDs for PARADYM RF JPN RDY models (EC, US & JPN compliance) VR, EMC LCIE report DR, EMC LCIE report CRT, EMC LCIE report SonR, EMC LCIE report VR, RADIO LCIE report DR, RADIO LCIE report CRT, RADIO LCIE report SonR, RADIO LCIE report All models, EMF (Human exposure) report SAR simulation report	REP2482A MISC1665A	These reports bear the whole of RF ZL70102 feature results with respect to STDs for Syndeli RF V2 DF4 & LCIE reports of precedence (EC, US & JPN compliance) VR, EMC LCIE report DR, EMC LCIE report CRT, EMC LCIE report SonR, EMC LCIE report VR, RADIO LCIE report DR, RADIO LCIE report CRT, RADIO LCIE report SonR, RADIO LCIE report All models, EMF (Human exposure) report SAR simulation report for Syndeli RF V2 DF4
7	REP2100A	This report bears the whole qualification tests & previous results performed by the LCIE on PARADYM RF JPN RDY and rationales. VR, 45502 EN series LCIE report DR, 45502 EN series LCIE report CRT, 45502 EN series LCIE report SonR, 45502 EN series LCIE report	REP2483A	This report bears the whole qualification tests results performed by the LCIE on Syndeli RF V2 DF4 (high & low profile header) & LCIE reports of precedence VR, 45502 EN series LCIE report DR, 45502 EN series LCIE report CRT, 45502 EN series LCIE report SonR, 45502 EN series LCIE report

Step	PARADYM RF JPN RDY source		Syndeli RF V2 DF4 V&V GENERAL PLAN	
	DHF Source	Test description	DHF Ref	Test description
8	PROTER1N	This document bears the tests protocol to be performed internally and by the LNE certified lab. for insuring ICD & CRT compliance with respect to EN45502 environmental tests requirements	PROTER1O	This document bears the tests protocol to be performed internally and by the LNE certified lab. for insuring Syndeli RF DF4 compliance with respect to EN45502
	REP1156A	This document bears the results of the whole qualification tests performed internally and by the LCIE certified lab. for insuring ICD & CRT compliance with respect to EN45502 environmental tests requirements	REP2481A MISC1775A	These documents bear the results of the whole qualification tests performed internally, by the LNE certified lab., and rationale to demonstrate previous tests results are eligible for ensuring Syndeli RF DF4 compliance with respect to EN45502
9	PROTER4J	This document bears the tests protocol to be performed to ensure ICD & CRT compliance with respect to IS-1 and DF-1 standards	PROTER22A	This document bears the tests protocol to be performed to ensure Syndeli RF V2 DF4 compliance with respect to IS-1 and DF-4 standards
	REP1155B	These documents bear the whole qualification tests & results performed to ensure ICD & CRT compliance with respect to IS-1 and DF-1 standards	REP2430A	These documents bear the whole qualification tests & results performed to ensure ICD & CRT compliance with respect to IS-1 and DF-4 standards
10	MISC0482A	This document bears the protocols of tests to be performed to assess the biological effects of the PARADYM RF following the requirements of ISO 10993: Biological Evaluation of Medical Devices, as well as the tests results demonstrating ICD & CRT compliance to this standard.	MISC1584A	This document bears the protocols of tests to be performed to assess the biological effects of the Syndeli RF V2 DF4 following the requirements of ISO 10993: Biological Evaluation of Medical Devices, as well as the tests results demonstrating ICD & CRT compliance to this standard.
11	PLAN0950A	This document bears the protocols of tests to be performed to validate the Ethylene Oxide Sterilization BC1 cycle	MISC1611A	This document bears the rational which demonstrates the results obtained in SYRF V1 are fully applicable to SYRF V2 DF4
	REP1308B	This document bears the tests results of the Ethylene Oxide Sterilization BC1 cycle validation		

Step	PARADYM RF JPN RDY source		Syndeli RF V2 DF4 V&V GENERAL PLAN	
	DHF Source	Test description	DHF Ref	Test description
12	PLAN0670C	This document bears the protocol of tests to be performed to validate the DF1 headers SonR CRT-D, CRT-D, DR and VR versions	PLAN1515B	This document bears the protocol of tests & measurements to be performed to validate the DF4 headers SonR CRT-D, CRT-D, DR and VR versions
	REP0738C REP0739C REP0852D REP0853D	These documents bear the whole component qualification results of the DF1 headers SonR CRT-D, CRT-D, DR and VR versions	REP2424A REP2427A	These documents bear the whole component qualification results of the DF4 headers SonR CRT-D, CRT-D, DR and VR versions
13	PLAN0669A	This document bears the protocol of tests to be performed to validate the DF1 wedge	PLAN1519A	This document bears the protocol of tests & measurements to be performed to validate the DF4 wedge
	REP0737A	This document bears the whole component qualification results of the DF1 wedge	REP2428A	This document bears the whole component qualification results of the DF4 wedge
14	QC00673A	This document bears the whole component qualification results of the DF1 top silicone cap	PLAN1520A	This document bears the protocol of tests & measurements to be performed to validate the DF4 top silicone cap
			REP2429A	This document bears the whole component qualification results of the DF4 top silicone cap