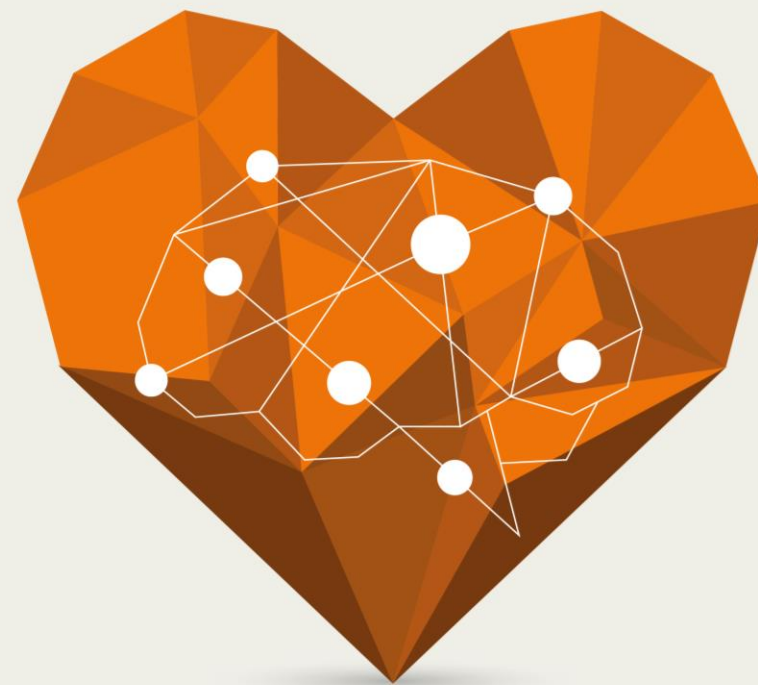


AFNOR SPEC 2311: Towards a standard for using COTS in active implantable medical devices



ACCEDE | ESCCON

2025

Seville - Spain
25 to 27th March

ALTER



TAME-COMPONENT

TRONICO

SUMMARY

○ WHO

- Tame-Component at a glance

○ WHY

- Genesis
- Market needs vs. Lack of existing standards

○ HOW

- Project core steps

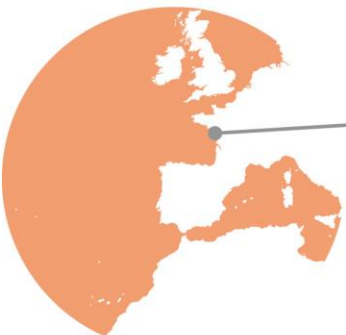
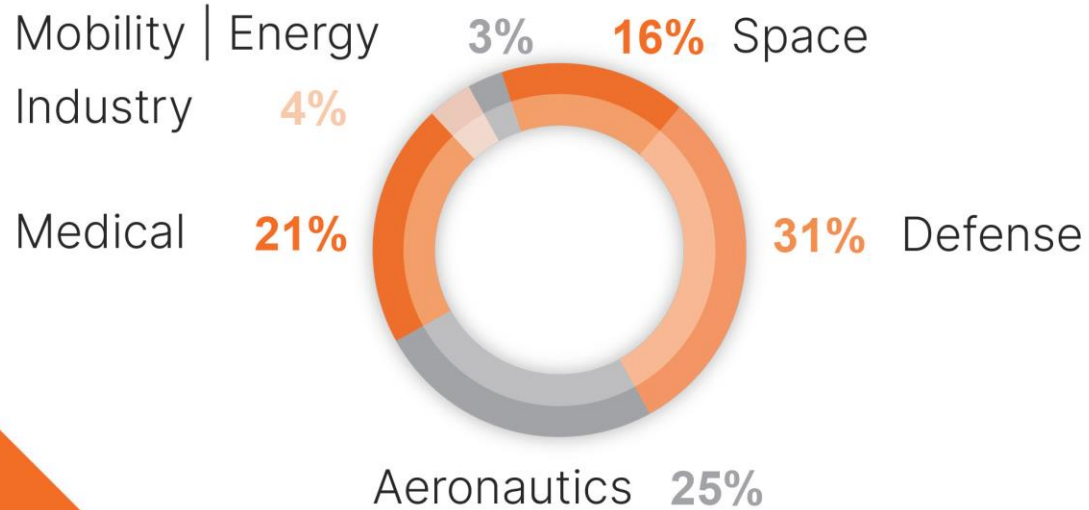
○ WHAT

- A qualification and surveillance methodology
- AFNOR SPEC 2311: general considerations

○ Questions & Answers

TAME-COMPONENT AT A GLANCE

Our activities



Our location

Headquarters
FRANCE - Saint-Philbert-de-Bouaine



Tame-Component, electronic components center of expertise

Customized solutions to qualify and maintain your electronics. Tame-Component recommends and implements your test and analysis solutions.



Laboratory surface

250 m²



Our people

27

- 30 % engineers & doctors
- 30 % technicians
- 40 % operators



Quality of service

COFRAC accredited
ISO IEC 17025
OQD: 0 ppm
OTD: 88%



A manufacturer's vision

Traceability ++
Pragmatism
Multi-sector expertise



Services

Incoming inspection
Qualification
Failure Analysis
Obsolescence Management
Secure storage

WHY

In 2016, we were approached by a manufacturer of artificial hearts seeking to test components for their product.

Their specifications were derived from space applications, but not compatible with their production volumes (1000 units/year).

- No standards for Active Implantable Medical Devices (AIMD)

AEC-Q Components were selected – more stringent operating conditions than the customer's specification.

Additional Lot Acceptance Testing (LAT) conducted.



WHY

We started receiving similar inquiries from other clients in the same industry, occasionally with inadequate initial component selections due to limited reference points.

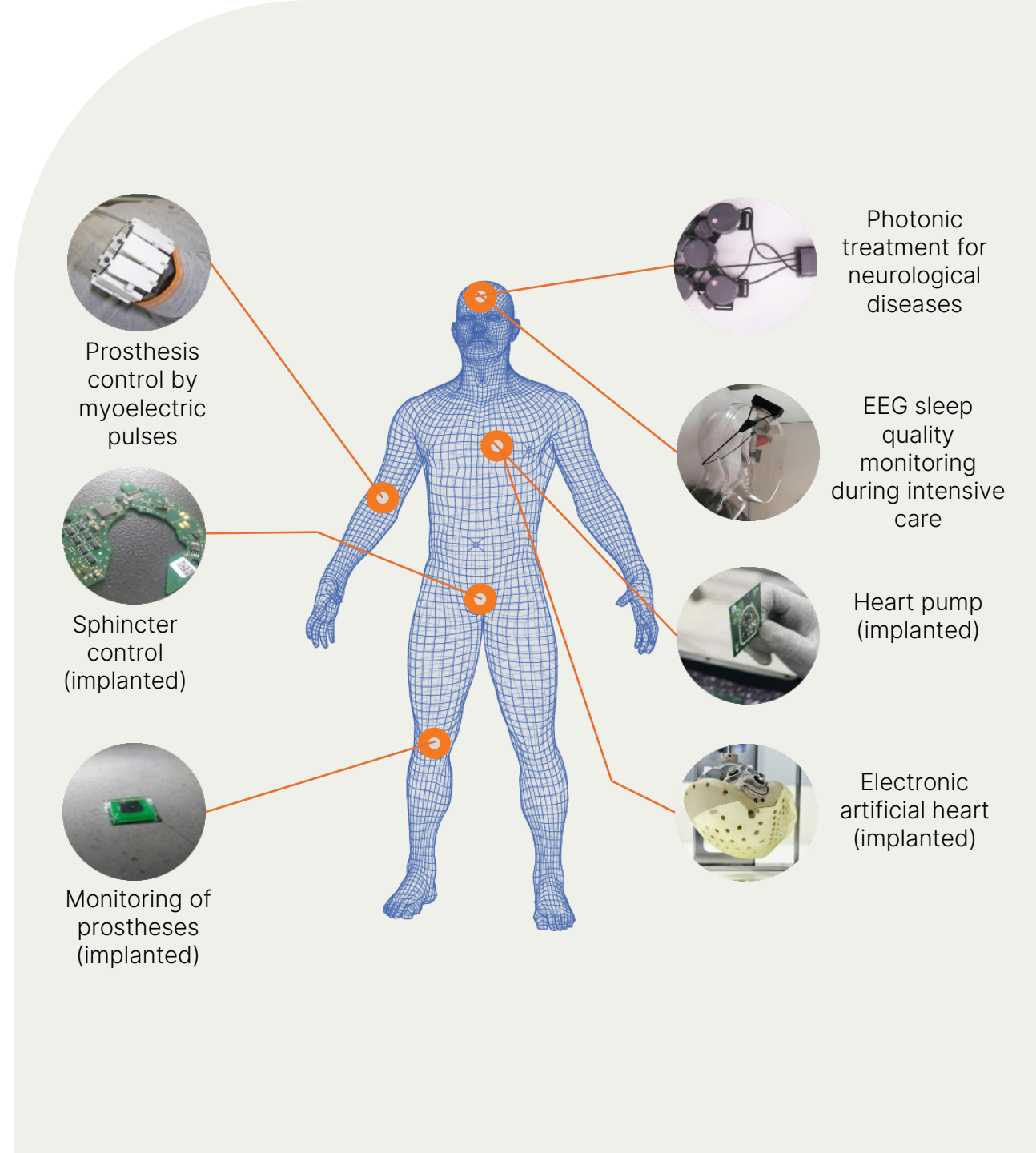
As a result, we initiated the **RECOME Project: Reliability of Electronic COmponents for MEDical devices.**



RECOME

Reliability of Electronic COmponents for MEDical devices

TAME-COMPONENT
TRONICO



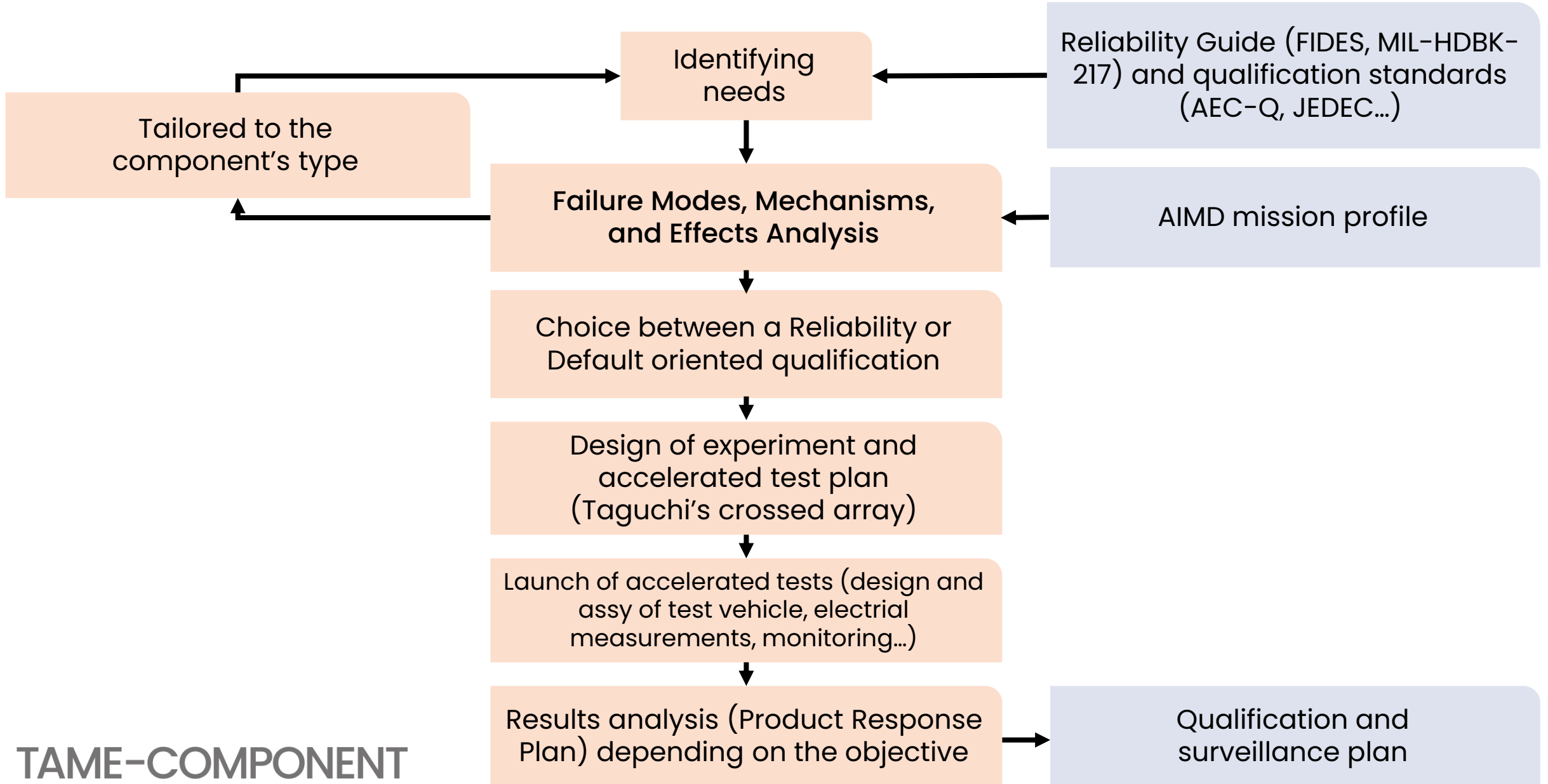
HOW

RECOME Project : 3 Core steps

1. **Bringing together the key actors from the industry** within the "RECOME Club" to identify all constraints and needs (regulatory, normative, design, manufacturing, standard use, ...)
Around 60 members, including component manufacturers, AIMD designers, component laboratories, end users, trade associations ...
2. **Defining tests plans and launching tests** on components (following slides)
3. **Launching of a Working Group** with some members of the "Recome Club" in view of creating an industry standard, with the help of Afnor.



HOW : METHODOLOGY



HOW : EXAMPLE OF MLCC PRODUCT-PLAN

Latin Hypercube →

ALT N° (j)	1	2	3	4	5
Voltage ratio	0	0.4	0.8	1.2	1.6
RH (%)	75	85	30	0	60
Temperature (°C)	30	85	60	120	10

DOE N° (i)	Dielectric	Termination	Size	CV	Responses				
1	X7R	Rigid	0603	Cat1					
2	X7R	Rigid	0603	Cat2					
3	X7R	Rigid	0603	Cat3					
...									
13	X7R	Flex	0805	Cat1					
14	X7R	Flex	0805	Cat2					
15	X7R	Flex	0805	Cat3					
...									
25	C0G	Rigid	1206	Cat1					
26	C0G	Rigid	1206	Cat2					
27	C0G	Rigid	1206	Cat3					
28	C0G	Flex	0603	Cat1					
29	C0G	Flex	0603	Cat2					
30	C0G	Flex	0603	Cat3					
...									
39	C0G	Rigid	0402	Cat1					
40	C0G	Rigid	0402	Cat2					
41	X7R	Flex	0402	Cat1					
42	X7R	Flex	0402	Cat2					
...									
45	X7R	Rigid	0201	Cat1					
46	X7R	Rigid	0201	Cat2					
47	C0G	Rigid	0201	Cat1					
48	C0G	Rigid	0201	Cat2					
49	X7R	Rigid	01005	Cat1					
50	X7R	Rigid	01005	Cat2					
51	C0G	Rigid	01005	Cat1					
52	C0G	Rigid	01005	Cat2					

Taguchi's crossed array →

- Each cell represents an ALT on 24 identical components
- Capacitance, dissipation factor and insulation resistance are measured on each component.
- 6 measurements steps: 0h, 200h, 400h, 600h, 800h, 1000h.
- Deterioration data of each component of each cell of the product-plan.

AFNOR SPEC 2311: WHAT IT CONTAINS

5.5 Multilayer CMS ferrite inductors

Table 7 - Qualification and Monitoring by stress type for Multilayer CLS ferrite inductors

N°	Class	Type of test by stress type	Reference source	Test conditions	Qualification		Surveillance		Acceptance criteria
					Number of Lots	Sampling level	Period	Sampling level	
1	A-2 and C	Visual and dimensional inspection*	IEC 60938-1:2021, 5.3		1	II	By lot	S-4	IEC 60938-1:2021, 5.3
4	A-1 and C	Electrical tests* - Resistive value - Impedance or inductance value	End user specification	Impedance or inductance measurement IAW manufacturer specified frequency and voltage/current	1	100%	By lot	S-4	Per manufacturer tolerances
8	C	Solderability	IEC 60938-1:2021, 5.16	$T_{\text{bath}} = 245 \pm 5^{\circ}\text{C}$; SAC 305 Bath (Pb-free) ; $t_{\text{imm}} = 3 \pm 0,3\text{s}$			By lot	S-2	95% of area IAW IEC 60068-2-58
10	B and C	Endurance	DOD - DSCC-DWG-03024 IEC 60938-1:2021	$I = 64\% \times I_n$; $T = 125^{\circ}\text{C}$; $t = 1000\text{h}^{***}$	3	48 **	Annual	24	Per manufacturer tolerances
14	B and C	Thermal Shock	IEC 60938-1:2021, 5.17 MIL-STD-202-107	10 cycles; $T = T_{\text{min}}/T_{\text{max}}$; plateaus based on specimen weight (MIL-STD-202-107) ; 5 min transition	1	24	Annual	24	Per manufacturer tolerances

NOTE 1:

* Non destructive test

** For AIMDs with a 10-year product life (see chapter 4.4)

*** The sample size for qualification is calculated with an acceleration factor of $FA = 3,65$ and a component temperature of 42°C in nominal conditions over a 10-year period.

NOTE 2:

I_n = nominal current

t_{imm} = immersion time

AFNOR SPEC 2311: WHAT IT CONTAINS

A method to **qualify** and **monitor**
the **reliability** of electronic components

Test protocols by component family

- ♥ SMD resistors
- ♥ SMD ceramic capacitors
- ♥ SMD tantalum capacitors
- ♥ SMD multilayer ferrite inductors
- ♥ SMD wound inductors
- ♥ Integrated circuits

Requirements for qualification test plans

- ♥ Batch of components tested
- ♥ Production requirements
- ♥ Test protocol requirements
- ♥ Sample size requirements
- ♥ Qualification acceptance criteria
- ♥ Reuse of a test sample

Environmental constraints

- ♥ Humidity
- ♥ Chemical constraints
- ♥ Mechanical stresses
- ♥ Electrical stresses
- ♥ Thermal stresses
- ♥ Radiative constraints

AFNOR SPEC 2311: WHAT IT CONTAINS

♥ Published **March 17, 2025**

♥ AFNOR SPEC is equivalent to **PAS** (Publicly Available Specification) of IEC Standardization system

			European regulation UE 1025/1012	
Public Inquiry	X	X	X	✓
Formal standardization commission	X	X	✓	✓
Consensus in the sense of standardization	X	✓	✓	✓
Opening	X	✓	✓	✓
Transparency	X	✓	✓	✓
	Private standard	Afnor Spec	XP Standard	Standard



Q&A



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