

5/1/2020

RE: PennEngineering Compliance and Process statement for EU MDR 2017/245 and Section 10.4.1 of the Regulation for substances.

**Scope:**

MDR Statement for PennEngineering® to show compliance/position for Medical Device EU 2017/745

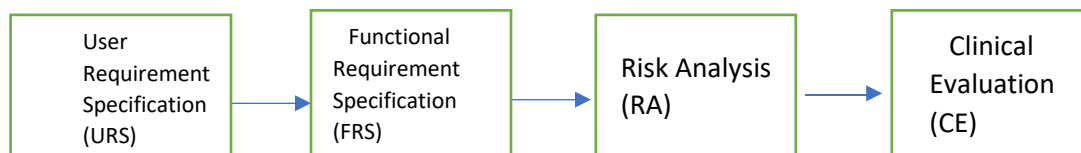
**Purpose:**

PennEngineering's compliance with EU 2017/245 Regulations for Medical Device. Other aspects of being an approved supplier for this industry.

**Key Elements:**

Governing ISO standard is ISO 13485: 1996, Section 10.4.1 for Material Composition  
Manufacturing locations' ISO 9001: 2015 certifications specific to risk analysis and QMS

Process basic Flow



**Reference:**

URS: a) What is the part being used for?

b) Is product being inserted into a person?

FRS: a) if we are supplying a standard part from the catalog we need to control it via YQ or some other designation to control changes and possibly location/process of manufacture

RA: a) Parts should go through at minimum the family template or part number specific APQP Process. This includes PFMEA and Control Plan work.

CE: a) Use of CAPA system to control risk and mitigation.

Global Harmonization Task Force (GHTF):

Appropriate risk management when application is known to PennEngineering®  
If we can know the application this would require APQP/PPAP of the part (at least internally)

**Reference...ISO 13485: 1996**

Clause 4: Establishment of a QMS (compliant? Yes)

Clause 6: Personnel have right skills and training (compliant? Yes)

Clause 8: Quality performance monitoring (compliant? Yes)

Clause 7: Development of procedures to identify and track products (compliant? Yes)

**Statement of Compliance:**

Article 18 of current EU MDR

Exceptions for full compliance are:

- Screws, Pins, Clips, etc.

Will retain data for 5 years

All parts provided by PennEngineering are compliant to Section 10.4.1 denoting substances for Regulation EU 2017/245.



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