Hi Steve,

I'm still strong involved in our audit but here first response to your questions -> see answers in red below.

Regards,
Marko

Von: steve.nixon.viamed@googlemail.com [mailto:steve.nixon.viamed@googlemail.com] **Im Auftrag von** Steve Nixon
An: Sproessel, Marko (GE0Y)
Cc: Wagner, Jessica (GE0Y)
Betreff: Information required for ISO auditors

Ref.
LISTE DER GRUNDL. ANFORDERUNGEN GEM. MDD 93/42/EWG / LIST OF ESSENTIAL REQUIREMENTS

Hi Marko

Further to the **List of Essential Requirements** that you previously supplied, is it possible for you to supply further information in order to try and satisfy our auditors.

Essential Requirements
I. ALLGEMEINE ANFORDERUNGEN

3. PMF 3.5 We need to know what is in this document . We only have:
CE Cert Test Report: 413097_2 SUV 80601-2-55 OOMXXX
Wismar, 2015-07-01
Test Report #413.097.3 Mechanical Strength Tests on Oxygen Sensors

PMF 3.5 described the chapter 3.5 in our Product Master File (PMF) -> see template of PMF table of contents in attachment. In chapter 3.5 you can find in PMF the test report according to ISO 80601-2-55.

5. PMF 3.5.1 We need to know what is in this document .

Is the same -> here you can find the test report according to ISO 80601-2-55 (SEB test report).

6a. PMF 2.5 We need to know is this document the Clinical Evaluation Report OOMXXX-X (Except OOm109-X)

Yes - in chapter 2.5 of PMF you can find the clinical evaluation report.

7. CHEMISCHE, PHYSIKALISCHE UND BIOLOGISCHE EIGENSCHAFTEN Chemical, physical and biological properties

7.1 PMF 2.4 We need to know is this document the Clinical Evaluation Report OOMXXX-X (Except OOm109-X)
In chapter 2.4 of PMF you can find Risk Management File and in Chapter 2.5 clinical evaluation report.

7.2 We need a document on packaging and transport trials

There is no separate document for packaging and transport trials. The packaging form is established and proof since more than 10 years. So we have long-term experience without negative field response. Risks

during transport, storage and use of the product are evaluated in clinical evaluation, risk management file and also in safety data sheet of the oxygen sensors.

7.3 PHA 2.4 What is this document (It can be redacted to remove commercially sensitive information)

In chapter 2.4 of PMF you can find Risk Management File.

7.5 Instructions for use (are they just on the label)

Instructions for use you can find partly on sensor and packaging label and of course in the “Instruction for Use” document.

7.5 Safety data sheet (Is this only on the website)
At the moment we provide the Safety Data Sheet on customer demand -> see attachment.

Regards
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Steve

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