medídee®

SWISS MEDTECH

MDR@noon – e-IFU

What should you do? View of a consultant

01.21.2021 Delphine Huser

Senior associate

medídee®

« Implementing eIFU is no small task as it requires a structured approach with a dedicated project team composed of key company departments and functions. »

medídee®

Team creation and impact assessment

Marketing : Communication with customers, distributors, sales team

RAQA: Supplier management
QMS (SOP, WI …)
Software validation
Technical file (ERC, risk analysis, usability)
Conformity assessment

Manufacturing: Labelling/Packaging
Sterilization

Human resources: Training

medídee®

Notified bodies feedback (1)

- Website availability
  - Provision of historic data on website performance.
  - Geolocation Availability Test
- Usability data
  - How being sure that the content of the new labelling is understandable ?
- Risk analyses
  - if eIFU system not available, recommendation to keep a local copy of the paper IFU -> new risk
- Packaging
  - sterilization, label marking durability

medídee®

Notified bodies feedback (2)

- Information on how to request a paper IFU
  - the manufacturer needed to add a section to the eIFU page on this and show evidence of customer communication
- Paper IFU for eIFU
  - multilingual paper instruction for the eIFU system (one page) to be sent with each device, the manufacturer went along but will challenge this after 12 months as not needed
- IFU content
  - Proof that the content of the IFU and eIFU remained the same

medídee®

Delphine Huser

delphine.huser@medidee.com

+41 79 779 18 08