SMEs and the need for Textile Care legislation and Standards

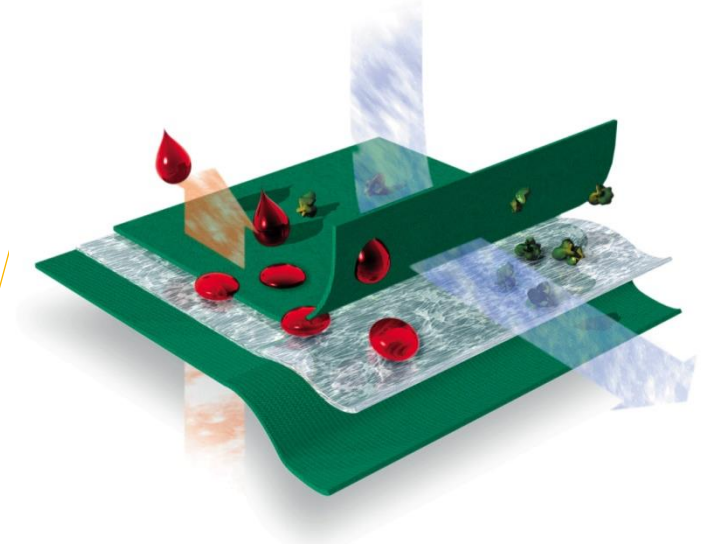
ISO / TC 94 / SC 13 / WG 6: Protective clothing against heat and fire, foul weather and cold

ISO 20384: Surgical Drapes & Gowns used as medical devices

Sven Schöppe, project leader ISO 20384

Protective Clothing in Europe

Protective clothing and covering used as Medical Devices:



Used in every hospital in Europe

- **Surgical gowns and surgical drapes for surgical procedures**
- **Isolation gowns for ward staff and visitors**

Used in a wide range of first aid / emergency applications
Used in industries like pharmaceutical, food, cosmetics

Providing protection for health care workers and patients by preventing the transfer of infective agents using effective barrier properties

Supplied to users as single use (globally produced) or reusable (locally produced and reprocessed) products (medical devices) which support circular economy

Manufacturers of Medical Devices are mostly SME

The majority of MD manufacturers are SME, just as the majority of European companies are:

- over 25.000 MedTech companies
- with more than 575.000 Employees
- and 95% representing SME structures
- produce approx. 500.000 different medical products and technologies for the benefit of patient and user

These companies are highly impacted by the current changes of the EU regulatory system:

- from: Directive 93/42/EEC on medical devices
- to: Regulation (EU) 2017/745 on medical devices (MDR),
  - which entered into force on 25/5/2017
  - and to which manufacturers shall be fully compliant by 26/5/2020

Manufacturers of Medical Devices rely heavily on Harmonised standards - today

because they provide a manageable basis to declare conformity to MDDs basic safety requirements as

„Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation."

(https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en)

The Official Journal EU currently (17/11/2017) lists about 300 Harmonised Standards for Medical Devices.

Today, several mandates provide basis for harmonisation of standards under MDD.

Harmonised standards will require a specific Standardisation Request - tomorrow

As a result of Elliott Case / Anstar Case (C-630/16 Anstar) with relevant Court Judgements, e.g.:

- *"[…] harmonised standards are to be established by the European standardisation bodies on the basis of requests issued by the Commission […]"*
- *„[…] the Commission must assess the conformity of harmonised standards established by the European standardisation bodies with the relevant mandates […]"*

European Commission currently restructures the procedures for requesting and drafting of standards:

A first standardisation mandate (draft) discussed with MDCG (Medical Devices Coordination Group) and NBOG (Notified Bodies Operation Group) led to:

- A need for prioritization of standards for the first mandate with focus on horizontal standards for MD

Now the game will change for Manufacturers of Medical Devices

With the first standardisation mandate focus is on:

- EN ISO 13485 (MD, Quality Management Systems, Requirements for regulatory purposes)
- EN ISO 14155 (Clinical investigation of medical devices for human subjects - Good clinical practice)
- EN ISO 14971 (Medical devices - Application of risk management to medical devices)
- EN ISO 15223 (MD - Symbols to be used with MD labels, labelling and information to be supplied)
- EN ISO 10993-XX (Biological evaluation of medical devices)
- IEC 60601-1-XX (Medical electrical equipment)

as MDCG and NBOG wish them to be available by 30/9/29019

Submission of the draft mandate for a vote by the Standardisation Committee and adoption procedure in the Commission expected for 1st half of 2019

Harmonisation of further standards postponed but not excluded - future mandates with strict procedures

In abscence of vertical Harmonised standards, efforts and costs for SME manufacturers are on the rise

- Conformity assessment will become more difficult for especially manufacturers as they have to widen their Technical files proving conformity in abscence of conformity assumption through HAS
- Notfied Bodies will assess conformity with focus on (if not ONLY) horizontal harmonised Standards for Quality and Risk Management
- No agreed performance requirements for products regarded as „harmonised“ will be available for the time being (until further mandates are given)
- Purchasers of Medical Devices will have more difficulties in comparing products with no harmonised product standards at hand, resulting in uncertainty

- Future standardisation mandates:
  - Agreements on frequency and time-lines pending
  - Rigid procedures to be followed by ESOs, HAS Consultants, external Consultant E&Y

Help from Commission appreciated by SME

- Please keep on supporting SBS and SME by:

- Making it possible for SME to conform to regulation by harmonised standards
- Making sure that also MDCG, NBOG, ESOs, NSOs keep SME interests in mind, that standards and innovation go hand in hand and that standardisation mandates will not prevent or stop innovation
- Keeping a focus on European views in standardisation and keeping a strong voice of standardisation in Europe instead of handing it over to the international ISO community
  - Example 1: tendency to „de-link“ standards from Vienna Agreement (Annex ZA)
  - Example 2: TC 251 „Health Informatics“ – approx. 100 projects, mostly ISO