ТЕХНИЧЕСКАЯ ДОКУМЕНТАЦИЯ ДЛЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ - КОНТРОЛЬНЫЙ СПИСОК В СООТВЕТСТВИИ С ПРИЛОЖЕНИЯМИ II И III MDR (EU) 2017/745

1. DEVICE DESCRIPTION

- ☐ Name, General Description, Basic UDI-DI
- ☐ Intended use, claims, patients, users, conditions, contraindications, warnings
- ☐ Operating principles & mode of action
- ☐ Classification including rule justification, rationale for classification as a device
- ☐ Description, configuration, variants, accessories, other devices and combinations
- ☐ Key functional elements (parts/formulation/composition/functionality)
- ☐ Raw materials (of key functional elements & of parts with indirect/direct body contact)
- ☐ Technical Specifications (Features/dimensions/ performance attributes in specs made available to user)
- ☐ Previous generations & similar devices on markets

2. INFORMATION SUPPLIED

- ☐ Labels
- ☐ IFUs

3. DESIGN & MANUFACTURING

- ☐ Design Stages applied (Design Control)
- ☐ Design & Manufacturing specifications
- ☐ Manufacturing processes, process validations, adjuvants & continuous monitoring
- ☐ Final product testing / Quality Control Plan*
- ☐ Site identification (All sites, suppliers, subcontractors with design/manufacturing actitivies)

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS (GSPRS)

- ☐ List of applied standards including Common Specifications
- ☐ GSPR Checklist / Matrix
- ☐ GSPR link to verification/validation including precise identity of evidence documents for each harmonized standard and Common Specification

5. RISK MANAGEMENT

- ☐ Risk Management Plan
- ☐ Risk Management Methods, e.g. Preliminary Hazard Analysis, D-FMEA, P-FMEA, FTA, HAZOP, HACCP
- ☐ Risk Management Report, including benefit-risk analysis

6. DESIGN VERIFICATION & VALIDATION

VALIDATION DATA

- ☐ Clinical Evaluation Plan & Report
- ☐ Usability 62366*

V&V SUMMARY REPORT

VERIFICATION DATA

- ☐ Performance and Safety Test Results
- ☐ Physical, Chemical & Microbiological Characterization
- ☐ Biocompatibility 10993-X
- ☐ Stability & Shelf Life
- ☐ Reprocessing
- ☐ Electrical Safety & EMC 60601-X
- ☐ Software Verification & Validation 62304
- ☐ Information on test design, test protocols, data analysis methods, data summaries and test conclusions

7. POST-MARKET SURVEILLANCE (ANNEX III)

- ☐ Post Market Clinical Follow Up (PMCF) Plan & Report
- ☐ PMS Plan & Report (see Annex III of (EU) 2017/745
- ☐ Periodic safety update report (PSUR)

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