CONFORMITY ASSESSMENT PROCEDURES

As described in Article 52 of the MDR (EU) 2017/745

CLASS I

- Non-sterile/ Non-measuring function/ Non-reusable surgical instrument
  - Technical Documentation Annex II & III — No review by NB
    - Declaration of Conformity (DoC) Annex IV
      - CE
- Sterile/ Measuring function/ Reusable surgical instrument
  - Technical Documentation Annex II & III — Limited review by NB
    - OR
      - Annex IX QMS (Only aspects related to sterility/metrology/reuse)
      - Annex XI Part A Production Quality Assurance (Only aspects related to sterility/ metrology/ reuse)
    - Declaration of Conformity (DoC) Annex IV
      - CE XXXX

CLASS IIa

- Technical Documentation Annex II & III — Review per Annex IX Chapter II Section 4
  - OR
    - Annex IX Chapter I, III QMS
    - Annex XI Part A Production Quality Assurance Section 10
    - Annex XI Part B Product Verification Section 18
  - Declaration of Conformity (DoC) Annex IV
    - CE XXXX

CLASS IIb

- Technical Documentation Annex II & III — Review per Annex IX Chapter II Section 4
  - OR
    - Annex IX Chapter I, III QMS
    - Annex X Type Examination
      - OR
        - Annex XI Part A Production Quality Assurance
        - Annex XI Part B Product Verification
  - Clinical Evaluation Consultation Procedure per Article 54 *
  - Declaration of Conformity (DoC) Annex IV
    - CE XXXX

CLASS III

- Technical Documentation Annex II & III — Review per Annex IX Chapter II
  - OR
    - Annex IX Chapter I, II, III QMS
    - Annex X Type Examination
      - OR
        - Annex XI Part A Production Quality Assurance
        - Annex XI Part B Product Verification
  - Clinical Evaluation Consultation Procedure per Article 54 *
  - Declaration of Conformity (DoC) Annex IV
    - CE XXXX

CUSTOM MADE DEVICES

- EXCEPT CLASS III IMPLANTABLE
  - Annex XIII Documentation
- CLASS III IMPLANTABLE
  - Annex XIII Documentation
    - OR
      - Annex IX Chapter I QMS
      - Annex XI Part A Production Quality Assurance
  - Draw statement as per Annex XIII Section I

*) only for Class III implantable devices or Class IIb active devices intended to administer/remove medicinal products

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