

### Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	General requirements for stent systems
4.1	General
4.2	Type of stent
4.3	Materials of construction for stent system
4.4	Configuration and size designation for stents and stent systems
4.5	Intended clinical use designation
4.6	Balloon designation
5	Intended performance
6	Design attributes
6.1	General
6.2	Stent system
6.3	Stent
6.4	Stent system and stent
6.5	Coating on delivery system or stent
6.6	Coating on stent
6.7	Absorbable stent or coating
6.8	Drug-eluting stent
7	Materials
8	Design evaluation
8.1	General
8.2	Sampling
8.3	Conditioning of test samples
8.4	Reporting
8.5	Bench and analytical tests
8.5.1	Stent system and delivery system
8.5.1.1	Balloon testing
8.5.1.1.1	Balloon deflation time
8.5.1.1.2	Balloon rated burst pressure
8.5.1.1.3	Balloon rated fatigue
8.5.1.1.4	Dogboning
8.5.1.2	Dimensional verification of stent system
8.5.1.3	Dislodgement force (pre-mounted, balloon-expandable stents)
8.5.1.4	Force to deploy (self-expanding stents)
8.5.1.5	Particulate generation
8.5.1.5.1	Acute particulate generation
8.5.1.5.2	Chronic particulate generation
8.5.1.6	Profile effect/flaring (balloon-expandable stents)
8.5.1.7	Simulated use
8.5.1.8	Tensile bond strength
8.5.1.9	Torsional bond strength

8.5.1.10	Haemostasis
8.5.1.11	Biocompatibility
8.5.1.12	Sterilization assurance
8.5.1.13	Visibility
8.5.2	Stent
8.5.2.1	General and corrosion
8.5.2.2	Fatigue and durability — Computational analyses
8.5.2.3	Fatigue and durability — in vitro testing
8.5.2.3.1	General considerations
8.5.2.3.2	Radial fatigue and durability
8.5.2.3.3	Axial fatigue and durability
8.5.2.3.4	Bending fatigue and durability
8.5.2.3.5	Torsional fatigue and durability
8.5.2.3.6	Compression fatigue and durability
8.5.2.4	Patency-related tests
8.5.2.4.1	General and compression resistance to a perpendicularly-applied load (self-expanding stent for a venous or non-aortic, non-coronary or non-renal arterial implant location)
8.5.2.4.2	Crush resistance with perpendicularly applied load (balloon-expandable stent for a venous or non-aortic, non-coronary or non-renal arterial implant location)
8.5.2.4.3	Crush resistance with radially applied load (balloon-expandable stent for any implant locations)
8.5.2.4.4	Radial force (self-expanding stent for any implant locations)
8.5.2.4.5	Kink resistance (flexibility)
8.5.2.4.6	Stent-free surface area and stent outer surface area
8.5.2.5	Sizing-related testing
8.5.2.5.1	Dimensional verification of the stent
8.5.2.5.2	Stent diameter to balloon inflation pressure (balloon-expandable stents)
8.5.2.5.3	Stent length
8.5.2.5.4	Recoil (balloon-expandable stents)
8.5.2.6	Magnetic resonance imaging (MRI) safety
8.5.2.7	Stent and an endovascular prosthesis in combination
8.5.2.7.1	General and corrosion for a stent and an endovascular prosthesis used in combination
8.5.2.7.2	Fatigue and durability for a stent and an endovascular prosthesis used in combination
8.5.2.7.3	Patency-related tests for a stent used in combination with an endovascular prosthesis
8.5.2.7.4	Separation force between a stent and an endovascular prosthesis
8.5.2.7.5	Simulated use for a stent and an endovascular prosthesis used in combination
8.5.2.7.6	MR for a stent and an endovascular prosthesis used in combination
8.5.2.7.7	Visibility
8.5.3	Absorbable stents and stents containing an absorbable coating
8.5.4	Coating on a delivery system
8.5.5	Coating on a stent
8.5.6	Drug-containing stent
8.6	Preclinical in vivo evaluation
8.6.1	Purpose
8.6.2	Specific aims
8.6.3	Protocol considerations
8.6.4	Data acquisition
8.6.5	Test report and additional information
8.7	Clinical evaluation
8.7.1	Purpose
8.7.2	Specific aims
8.7.3	Protocol considerations
8.7.4	Data acquisition
8.7.5	Final report
9	Post-market surveillance
10	Manufacturing
11	Sterilization
11.1	Products supplied sterile
11.2	Sterilization residuals
12	Packaging

- 12.1 General
- 12.1.1 General
- 12.1.2 Unit container
- 12.1.3 Outer container
- 12.1.4 Shipping container
- 12.1.5 Maintenance of sterility in transit
- 12.2 Labelling
- 12.2.1 Container label
- 12.2.2 Stents without delivery systems
- 12.2.3 Stent systems (stents with delivery system)
- 12.2.4 Record label
- 12.3 Information supplied by the manufacturer
- 12.3.1 General
- 12.3.2 Information and instructions for use for stents and/or stent systems

**Annex A (informative) Relationship between testing requirements, device attributes, and potential failure modes and guidance for the creation of a device evaluation strategy**

- A.1 Device evaluation strategy introduction and rationale for bench testing and analyses
- A.2 Device-specific evaluation strategy table
  - A.2.1 General and focused device evaluation strategy
    - A.2.1.1 Identification of potentially affected attributes for focused device evaluation strategy
      - A.2.1.1.1 In vivo environment
      - A.2.1.1.2 Device design or intended use comparison
    - A.2.1.2 Focused device evaluation strategy table
  - A.2.2 Comprehensive device evaluation strategy
- A.3 Testing summary

**Annex B (informative) Description of clinical effects of failure**

**Annex C (informative) Description of device effects of failure**

**Annex D (informative) Test methods**

- D.1 General
- D.2 Sampling
- D.3 Conditioning of test samples
- D.4 Reporting
- D.5 Test method development guidance
  - D.5.1 General
  - D.5.2 Stent system and delivery system
    - D.5.2.1 General
      - D.5.2.2 Balloon testing
        - D.5.2.2.1 General
          - D.5.2.2.2 Balloon deflation time
            - D.5.2.2.2.1 Purpose
              - D.5.2.2.2.2 Materials
              - D.5.2.2.2.3 Sampling
              - D.5.2.2.2.4 Conditioning
              - D.5.2.2.2.5 Test method
              - D.5.2.2.2.6 Expression of results
              - D.5.2.2.2.7 Test report
            - D.5.2.2.3 Balloon rated burst pressure
              - D.5.2.2.3.1 Purpose
              - D.5.2.2.3.2 Materials
              - D.5.2.2.3.3 Sampling
              - D.5.2.2.3.4 Conditioning
              - D.5.2.2.3.5 Test method
              - D.5.2.2.3.6 Expression of results
              - D.5.2.2.3.7 Test report
            - D.5.2.2.4 Balloon rated fatigue
              - D.5.2.2.4.1 Purpose
              - D.5.2.2.4.2 Materials
              - D.5.2.2.4.3 Sampling
              - D.5.2.2.4.4 Conditioning
              - D.5.2.2.4.5 Test method

- D.5.2.2.4.6 Expression of results
- D.5.2.2.4.7 Test report
- D.5.2.2.5 Dogboning
  - D.5.2.2.5.1 Purpose
  - D.5.2.2.5.2 Materials
  - D.5.2.2.5.3 Sampling
  - D.5.2.2.5.4 Conditioning
  - D.5.2.2.5.5 Test method
  - D.5.2.2.5.6 Expression of results
  - D.5.2.2.5.7 Test report
- D.5.2.3 Dimensional verification of the stent system
  - D.5.2.3.1 Purpose
  - D.5.2.3.2 Materials
  - D.5.2.3.3 Sampling
  - D.5.2.3.4 Conditioning
  - D.5.2.3.5 Test method
  - D.5.2.3.6 Expression of results
  - D.5.2.3.7 Test report
- D.5.2.4 Dislodgement force (pre-mounted, balloon-expandable stents)
  - D.5.2.4.1 Purpose
  - D.5.2.4.2 Materials
  - D.5.2.4.3 Sampling
  - D.5.2.4.4 Conditioning
  - D.5.2.4.5 Test method
  - D.5.2.4.6 Expression of results
  - D.5.2.4.7 Test report
- D.5.2.5 Force to deploy (self-expanding stents)
  - D.5.2.5.1 Purpose
  - D.5.2.5.2 Materials
  - D.5.2.5.3 Sampling
  - D.5.2.5.4 Conditioning
  - D.5.2.5.5 Test method
  - D.5.2.5.6 Expression of results
  - D.5.2.5.7 Test report
- D.5.2.6 Acute particulate generation
  - D.5.2.6.1 Purpose
  - D.5.2.6.2 Materials
  - D.5.2.6.3 Sampling
  - D.5.2.6.4 Conditioning
  - D.5.2.6.5 Test method
  - D.5.2.6.6 Expression of results
  - D.5.2.6.7 Test report
- D.5.2.7 Profile effect/flaring (balloon-expandable stents)
  - D.5.2.7.1 Purpose
  - D.5.2.7.2 Materials
  - D.5.2.7.3 Sampling
  - D.5.2.7.4 Conditioning
  - D.5.2.7.5 Test method
  - D.5.2.7.6 Expression of results
  - D.5.2.7.7 Test report
- D.5.2.8 Simulated use
  - D.5.2.8.1 Purpose
  - D.5.2.8.2 Materials
  - D.5.2.8.3 Sampling
  - D.5.2.8.4 Conditioning
  - D.5.2.8.5 Test method
  - D.5.2.8.6 Expression of results
  - D.5.2.8.7 Test report
- D.5.2.9 Tensile bond strength
  - D.5.2.9.1 Purpose
  - D.5.2.9.2 Materials
  - D.5.2.9.3 Sampling
  - D.5.2.9.4 Conditioning
  - D.5.2.9.5 Test method

- D.5.2.9.6 Expression of results
- D.5.2.9.7 Test report
- D.5.2.10 Torsional bond strength
  - D.5.2.10.1 Purpose
  - D.5.2.10.2 Materials
  - D.5.2.10.3 Sampling
  - D.5.2.10.4 Conditioning
  - D.5.2.10.5 Test method
  - D.5.2.10.6 Expression of results
  - D.5.2.10.7 Test report
- D.5.2.11 Visibility
  - D.5.2.11.1 Purpose
  - D.5.2.11.2 Materials
  - D.5.2.11.3 Sampling
  - D.5.2.11.4 Conditioning
  - D.5.2.11.5 Test method
  - D.5.2.11.6 Expression of results
  - D.5.2.11.7 Test report
- D.5.3 Stent
  - D.5.3.1 Corrosion
    - D.5.3.1.1 Purpose
    - D.5.3.1.2 Materials
    - D.5.3.1.3 Sampling
    - D.5.3.1.4 Conditioning
    - D.5.3.1.5 Test method
    - D.5.3.1.6 Expression of results
    - D.5.3.1.7 Test report
  - D.5.3.2 Fatigue and durability — Computational analyses
    - D.5.3.2.1 Purpose
    - D.5.3.2.2 Model inputs and tools
    - D.5.3.2.3 Analysis
    - D.5.3.2.4 Expression of results
    - D.5.3.2.5 Report
  - D.5.3.3 Fatigue and durability — in vitro testing
    - D.5.3.3.1 General
      - D.5.3.3.1.1 Purpose
      - D.5.3.3.1.2 Materials
      - D.5.3.3.1.3 Sampling
      - D.5.3.3.1.4 Conditioning
      - D.5.3.3.1.5 Test method
      - D.5.3.3.1.6 Expression of results
      - D.5.3.3.1.7 Test report
    - D.5.3.3.2 Radial fatigue and durability
      - D.5.3.3.2.1 Purpose
      - D.5.3.3.2.2 Materials
      - D.5.3.3.2.3 Sampling
      - D.5.3.3.2.4 Conditioning
      - D.5.3.3.2.5 Test method
      - D.5.3.3.2.6 Expression of results
      - D.5.3.3.2.7 Test report
    - D.5.3.3.3 Axial fatigue and durability
      - D.5.3.3.3.1 Purpose
      - D.5.3.3.3.2 Materials
      - D.5.3.3.3.3 Sampling
      - D.5.3.3.3.4 Conditioning
      - D.5.3.3.3.5 Test method
      - D.5.3.3.3.6 Expression of results
      - D.5.3.3.3.7 Test report
    - D.5.3.3.4 Bending fatigue and durability
      - D.5.3.3.4.1 Purpose
      - D.5.3.3.4.2 Materials
      - D.5.3.3.4.3 Sampling
      - D.5.3.3.4.4 Conditioning
      - D.5.3.3.4.5 Test method

- D.5.3.3.4.6 Expression of results
- D.5.3.3.4.7 Test report
- D.5.3.3.5 Torsional fatigue and durability
  - D.5.3.3.5.1 Purpose
  - D.5.3.3.5.2 Materials
  - D.5.3.3.5.3 Sampling
  - D.5.3.3.5.4 Conditioning
  - D.5.3.3.5.5 Test method
  - D.5.3.3.5.6 Expression of results
  - D.5.3.3.5.7 Test report
- D.5.3.3.6 Compression fatigue and durability
  - D.5.3.3.6.1 Purpose
  - D.5.3.3.6.2 Materials
  - D.5.3.3.6.3 Sampling
  - D.5.3.3.6.4 Conditioning
  - D.5.3.3.6.5 Test method
  - D.5.3.3.6.6 Expression of results
  - D.5.3.3.6.7 Test report
- D.5.3.4 Patency-related tests
  - D.5.3.4.1 Compression resistance to perpendicularly-applied load (self-expanding stent for a venous or non-aortic, non-coronary or non-renal arterial implant location)
    - D.5.3.4.1.1 Purpose
    - D.5.3.4.1.2 Materials
    - D.5.3.4.1.3 Sampling
    - D.5.3.4.1.4 Conditioning
    - D.5.3.4.1.5 Test method
    - D.5.3.4.1.6 Expression of results
    - D.5.3.4.1.7 Test report
  - D.5.3.4.2 Crush resistance with perpendicularly-applied load (balloon-expandable stent for a venous or non-aortic, non-coronary or non-renal arterial implant location)
    - D.5.3.4.2.1 Purpose
    - D.5.3.4.2.2 Materials
    - D.5.3.4.2.3 Sampling
    - D.5.3.4.2.4 Conditioning
    - D.5.3.4.2.5 Test method
    - D.5.3.4.2.6 Expression of results
    - D.5.3.4.2.7 Test report
  - D.5.3.4.3 Crush resistance with radially-applied load (balloon-expandable stents)
    - D.5.3.4.3.1 Purpose
    - D.5.3.4.3.2 Materials
    - D.5.3.4.3.3 Sampling
    - D.5.3.4.3.4 Conditioning
    - D.5.3.4.3.5 Test method
    - D.5.3.4.3.6 Expression of results
    - D.5.3.4.3.7 Test report
  - D.5.3.4.4 Radial force (self-expanding stents)
    - D.5.3.4.4.1 Purpose
    - D.5.3.4.4.2 Materials
    - D.5.3.4.4.3 Sampling
    - D.5.3.4.4.4 Conditioning
    - D.5.3.4.4.5 Test method
    - D.5.3.4.4.6 Expression of results
    - D.5.3.4.4.7 Test report
  - D.5.3.4.5 Kink resistance (flexibility)
    - D.5.3.4.5.1 Purpose
    - D.5.3.4.5.2 Materials
    - D.5.3.4.5.3 Sampling
    - D.5.3.4.5.4 Conditioning
    - D.5.3.4.5.5 Test method
    - D.5.3.4.5.6 Expression of results
    - D.5.3.4.5.7 Test report
  - D.5.3.4.6 Stent-free surface area and stent outer surface area
    - D.5.3.4.6.1 Purpose
    - D.5.3.4.6.2 Materials

- D.5.3.4.6.3 Sampling
- D.5.3.4.6.4 Conditioning
- D.5.3.4.6.5 Test method
- D.5.3.4.6.6 Expression of results
- D.5.3.4.6.7 Test report
- D.5.3.5 Sizing-related testing
  - D.5.3.5.1 Dimensional verification of stent
    - D.5.3.5.1.1 Purpose
    - D.5.3.5.1.2 Materials
    - D.5.3.5.1.3 Sampling
    - D.5.3.5.1.4 Conditioning
    - D.5.3.5.1.5 Test method
    - D.5.3.5.1.6 Expression of results
    - D.5.3.5.1.7 Test report
  - D.5.3.5.2 Stent diameter to balloon inflation pressure (balloon-expandable stents)
    - D.5.3.5.2.1 Purpose
    - D.5.3.5.2.2 Materials
    - D.5.3.5.2.3 Sampling
    - D.5.3.5.2.4 Conditioning
    - D.5.3.5.2.5 Test method
    - D.5.3.5.2.6 Expression of results
    - D.5.3.5.2.7 Test report
  - D.5.3.5.3 Stent length
    - D.5.3.5.3.1 Purpose
    - D.5.3.5.3.2 Materials
    - D.5.3.5.3.3 Sampling
    - D.5.3.5.3.4 Conditioning
    - D.5.3.5.3.5 Test method
    - D.5.3.5.3.6 Expression of results
    - D.5.3.5.3.7 Test report
  - D.5.3.5.4 Recoil (balloon-expandable stents)
    - D.5.3.5.4.1 Purpose
    - D.5.3.5.4.2 Materials
    - D.5.3.5.4.3 Sampling
    - D.5.3.5.4.4 Conditioning
    - D.5.3.5.4.5 Test method
    - D.5.3.5.4.6 Expression of results
    - D.5.3.5.4.7 Test report
- D.6 Supplement to D.5.2.3.2: Sample equations for calculation of the inner diameter (or radius) from the outer diameter (or radius)
  - D.6.1 Linear elastic mechanics with zero longitudinal strain (constant length)
  - D.6.2 Linear elastic mechanics with zero longitudinal stress (unconstrained length)
  - D.6.3 Nonlinear elastic mechanics

Page count: 114