| Device Feature | Product / product family | Equivalent device | Evaluation of equivalency |
|---|---|---|---|
| **Clinical** | | | |
| *According to MDR: The device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.* | | | |
| *According to MEDDEV 2.7/1 rev 4: - used for the same clinical condition (including whe* | | | |
| *similar severity and stage of disease, same medical indication), and - used for the sa* | | | |
| *purpose, and - used at the same site in the body, and - used in a similar population (thi* | | | |
| *to age, gender, anatomy, physiology, possibly other aspects), and - not foresee* | | | |
| *significantly different performances (in the relevant critical performances such as t* | | | |
| *clinical effect, the specific intended purpose, the duration of use, etc.)* | | | |
| Clinical condition/ indication | | | 1.1 |
| Intended purpose | | | 1.2 |
| Anatomical location | | | 1.3 |
| Population | | | 1.4 |
| Performance differences | | | 1.5 |
| Scientific justification w<br>performance of the dev<br>(use one row for eac<br>documentation as applicable) | | | Clinically significant difference<br>Yes / No |
| 1.1 | | | |
| 1.2 | | | |
| 1.3 | | | |
| 1.4 | | | |
| 1.5 | | | |
| **Technical** | | | |
| *According to MDR: The device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements.* | | | |
| *According to MEDDEV 2.7/1 rev 4: - be of similar design, and - used under the same conditions of use, and - have similar specifications and properties (e.g. physicochemical properties such as type and intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, surface texture, porosity,* | | | *nclusions such as* |
| *nitrocarburising, o* | | | *, and - have similar* |
| *principles of opera* | | | |
| Design | | | 2.1 |
| Conditions of use | | | 2.2 |
| Specifications and properties | | | 2.3 |

- including similar severity and stage of disease and have similar relevant critical performance.
- Manufacturers must take into consideration whether the intended user's competence or knowledge can have any implication for the safety, clinical performance and outcome. For example, a device intended for professional use and a device intended for home use, but for the same clinical condition or purpose, may have a different safety and performance profile due to the environment in which they are intended to be used.

You may identify more than one equivalent device to the device under evaluation: in that case you must add columns to the table listing the clinical, technical, and biological features for each of them, and perform the equivalence evaluation for each of them.

Considerations of equivalence shall be based on proper scientific justification!

- The conditions of use shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance between the device in question and the device presumed to be equivalent.
- This includes software algorithms in software driving or influencing the use of a device, and in software intended to be used alone. It is the functional principle of the software algorithm, as well as the clinical performance(s) and intended purpose(s) of the software algorithm, that shall be considered.

| | | | |
|---|---|---|---|
| Deployment method | | | 2.4 |
| Principle of operation / performance requirements | | | 2.5 |
| Scientific justification why there would be no clinically significant difference in the safety and clinical performance of the device, OR a description of the impact on safety and or clinical performance (use one row for each of the identified differences in characteristics, and add references to documentation as applicable) | | | Clinically significant difference Yes / No |
| 2.1 | | | |
| 2.2 | | | |
| 2.3 | | | |
| 2.4 | | | |
| 2.5 | | | |

**Biological**

*According to MDR: The device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables.*

*According to MEDDEV 2.7/1 rev 4: Use the same materials or substances in contact with the same human tissues or body fluids. Exceptions can be foreseen for devices in contact with intact skin and minor components of devices; in these cases risk analysis results may allow the use of similar materials taking into account the role and nature of the similar material.*

| | | | |
|---|---|---|---|
| Materials in contact with human tissues and body fluids | | | 3.1 |
| Similar kind and duration of contact with the same human tissues or body fluids | | | .2 |
| Similar release characteristics of substances including degradation products and leachables | | | 3.3 |
| Scientific justification why there would be no clinically significant difference in the safety and clinical performance of the device, OR a description of the impact on safety and or clinical performance (use one row for each of the identified differences in characteristics, and add references to documentation as applicable) | | | Clinically significant difference Yes / No |
| 3.1 | | | |
| 3.2 | | | |
| 3.3 | | | |
| Summary<br>In the circumstance that more than one non-significant difference is identified, provide a justification whether the sum of differences may affect the safety and clinical performance of the device. | | | |

- *Exceptions are not acceptable anymore!*
- The following should be considered: ISO 10993-1, Annex C of ISO 10993-18, ISO 10993-17, ISO 10993, Parts 13, 14 and 15