1. Please indicate the chosen equivalent device:
2. Is the presumed Equivalent device currently CE marked? If not, please discuss.
3. Please provide comparative diagrams of the predicate device and the proposed device:

|  |  |
| --- | --- |
| Predicate device | Proposed device |
|  |  |

1. Please provide the IFU for the equivalent device
2. What level of access do you have to the technical file of the equivalent device
3. For equivalence to be claimed, the 3 parameters of equivalence must be demonstrated – clinical, technical and biological – Please complete the tables below for clinical, technical and biological equivalence

|  |  |
| --- | --- |
| **Clinical equivalence** |  |
| Is the device used for the same clinical condition (including when applicable similar severity and stage of disease, same medical indication)  Please provide evidence |  |
| Is the device used for the same intended purpose  Please provide evidence |  |
| Is the device used at the same site in the body  Please provide evidence |  |
| Is the device used in a similar population (this may relate to age, gender, anatomy, physiology, possibly other aspects)  Please provide evidence |  |
| Is the device used not foreseen to deliver significantly different performances (in the relevant critical performances such as the expected clinical effect, the specific intended purpose, the duration of use, etc.)  Please provide evidence |  |

|  |  |
| --- | --- |
| **Technical Equivalence** |  |
| Are the devices of similar design  Please provide evidence |  |
| Is the device used under the same conditions of use  Please provide evidence |  |
| Does the device have similar specifications   * physicochemical properties such as type * intensity of energy, * tensile strength, viscosity, * surface characteristics, * wavelength, * surface texture, * porosity, * particle size, * nanotechnology, * specific mass, * atomic inclusions   Please provide evidence |  |
| Does the device use similar deployment methods  Please provide evidence |  |
| Does the device have similar principles of operation and critical performance requirements  Please provide evidence |  |

|  |  |
| --- | --- |
| **Biological Equivalence** |  |
| Does the device use the same materials or substances in contact with the same human tissues or body fluids  Please provide evidence |  |
| Have sourcing and manufacturing procedures been taken into consideration in relation to impurity profiles  Please provide evidence |  |
| Has the same animal model been used in testing  Please provide evidence |  |

1. Please describe the differences between the device under evaluation and the device presumed to be equivalent. Please explain in detail why these differences do not impact safety and performance of the data.
2. Has the medical device that is presumed to be equivalent been manufactured via a special treatment? If yes, does the treatment cause differences in respect to technical, clinical or biological equivalence?
3. Has the topic of equivalence been discussed in the CER? Please provide page numbers.
4. Please provide clinically relevant specifications and properties for the device under evaluation and the presumed equivalent device.
5. Please have the clinical expert review the data in this form and sign and date the form.