**Toxicological evaluation per ISO10993-17 - List of input data to provide**

**(IN ENGLISH PLEASE)**

***If the tested device represents other devices of a biological family, provide this information for each device of the family.***

|  |  |
| --- | --- |
| Name of the medical device |  |
| Description of the medical device (as mentioned in your technical file) |  |
| Picture or image of the medical device |  |
| Materials of the different parts of the device, with material standards applied |  |
| Composition of the packaging in contact with the device |  |
| Sterilization state of the device tested (method, dose range) |  |
| Stage of the device (eg. accelerating aging conditions, natural aging, etc…) |  |
| Complete list of references with designation / size |  |
| Intended use (as mentioned in your technical file) |  |
| Patient population | [ ]  adults[ ]  women[ ]  pregnant or lactating women[ ]  children (> 1 year to ≤ 16 years)[ ]  infants (≤ 1 year)[ ]  very low birthweight infants (≈1.5 kg)[ ]  very low birthweight neonates (e.g. preterm neonates) |
| Contact duration of each use |  |
| Use frequency |  |
| Total use duration |  |
| Categorization per ISO 10993-1 for type and duration of contact |  |
| Max number (or quantity if powder, gel, liquid…) of devices used per patient and per day. |  |
| For geometrical solid devices, surface area of the specimen tested (if the device is composed of different parts, provide information for each part) |  |
| For geometrical solid devices, maximum surface area in contact with the patient considering the range of references of the device (if the device is composed of different parts, provide information for each part) |  |
| What are the UF factors of your lab for the different analytical methods |  |
| Is the report for the US market? |  |
| Declaration of absence of substances listed in the Cohort of Concern families of ISO/TS 21726, in the raw materials and processing agents used |  |

… And of course the Chemical characterization report per ISO 10993-18 with extractables identified as much as possible with CAS number and quantities.