SGS

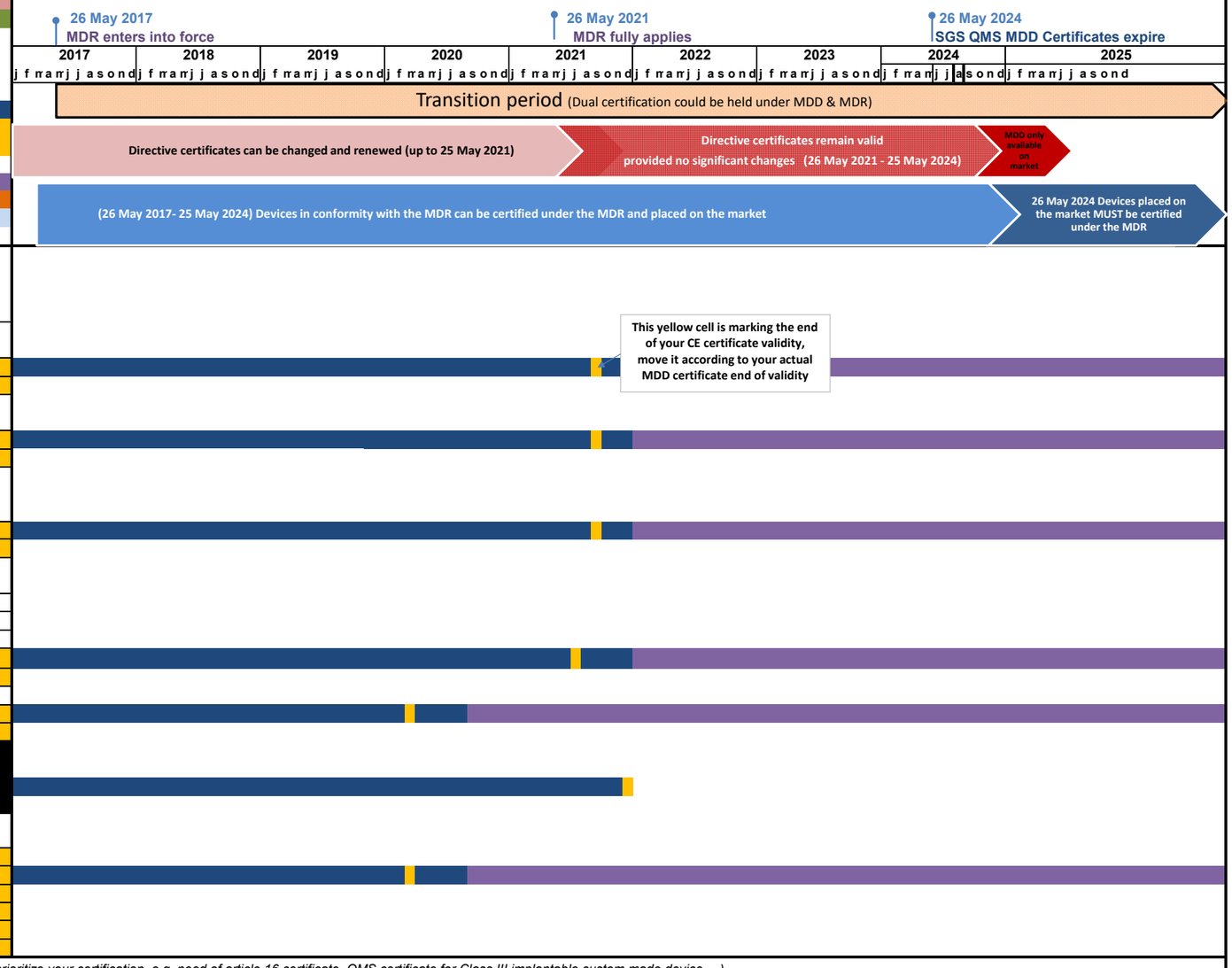
# TRANSITION PLAN TEMPLATE

**Tasks to complete your Transition Plan SGS:** **Manufacturer's Name**

1. List all devices listed on your current certificates in the cells in this colour, you can add rows to ensure your full device scope is identified
2. Identify any devices NOT being transitioned into MDR in the cells in this colour (row 50 onwards)
3. Identify any new devices not currently certified por entering into MDR scope (e.g. Annex XVI devices)in the cells in this colour
4. For each device list the certificate number in column B & indicate if the device changed of class from MDD to MDR in column C
5. For Class Im, Is, Ir & Class IIa device, document Implementing act 2017/2185 code in column E
6. For class IIb devices, list italian nomenclature device group code in column E (row 30 onwards) if known
7. List the MDD certificate expiry date for each device in column D
8. For each device / device fill (in this colour) the calendar cells upto the expiry date (see example)
9. For each device identify the date when technical documentation (TD) as per annex II & III will be submitted to SGS (enter date in column F)
10. Add the date when technical documentation is submitted into the calendar (see example)
11. for Class IIb Active intended to administer Medicines, Class IIB Implantable and Class III TD must be submits at least 6 months prior to expiry
12. For each device / device fill (in this colour)in your calendar dates after expiry of when you expect MDR certification
13. Identify and fill (in this colour) any devices where Dual certification could be held in MDD & MDR
14. Note:- SGS designation will depend on designation timescales outside of its control.
15. note:- Once complete send a copy with your MDR application form (LPMDREG1001) to your SGS local office

| MDR Classification (annex VIII) | MDD Certificate Number | Change of class ? | MDD Expiry date | | Date Technical documentation as per annex II & III will be submitted to SGS |
|---|---|---|---|---|---|
| Class Is & Im devices | Certificate Number | Yes / No | Expiry date | Implementing act 2017/2185 code | date |
| | | | | | |
| | | | | | |
| Class IIa devices | Certificate Number | Yes / No | Expiry date | Implementing act 2017/2185 code | date |
| | | | | | |
| | | | | | |
| Class IIb devices | Certificate Number | Yes / No | Expiry date | European MD nomenclature code | date |
| | | | | | |
| | | | | | |
| Class IIb Active intended to administer Medicines | Certificate Number | Yes / No | Expiry date | 100% review | date |
| | | | | | |
| | | | | | |
| Class IIb Implantable devices | Certificate Number | Yes / No | Expiry date | 100% review | date |
| | | | | | |
| | | | | | |
| Class III devices | Certificate number | Yes / No | Expiry date | 100% review | date |
| | | | | | |
| | | | | | |
| devices NOT being transitioned into MDR | Certificate Number | Yes / No | Expiry date | | |
| | | | | | |
| | | | | | |
| NEW devices not currently on MDD certifcates | | N/A | Classification | Associated code if relevant | date |
| Class Ir devices | | | | | |
| | | | | | |
| Annex XVI devices | | | | | |
| | | | | | |
| New device under development ... | | | | | |
| | | | | | |

**Transition Plan - Calendar**




**Comments** *(please add here any information that can be relevant to SGS to prioritize your certification e.g. need of article 16 certificate, QMS certificate for Class III implantable custom made device …)*