GUIDELINE TO COMPLETE THE TRANSITION PLAN FOR SGS CUSTOMERS

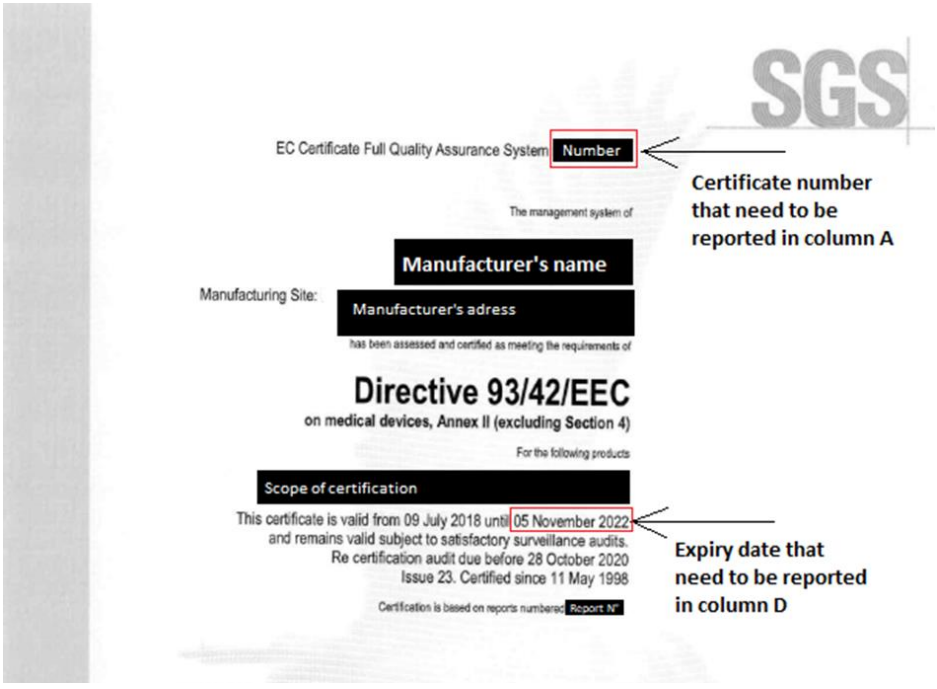
The transition plan has been created to collect all information SGS needs to support your transition from MDD to MDR, to allow us to plan availability of the correct qualified resources when you need them. As implementation of MDR requirements represent an important change we recommend you complete and return the transition plan as soon as possible so we can aim to start the MDR certification process around one year before the end of your current certificate validity.

For each product that is already CE marked by SGS that you wish to transfer from MDD to MDR, please complete the appropriate line of the table corresponding to the class of your device under MDR. If the class of your device is different between MDD and MDR, indicate “Yes” in column C. The required information on certificates are the one that are written on your actual MDD certificate:

1. For certificate number in column B, report the number of the CE certificate for each product listed in column A.

2. For expiry date in column D, report the “Valid until “date of the CE certificate for each product listed in column A. Once date of expiry date has been completed, fill in blue the corresponding line till expiry date of the corresponding product in the Transition plan - Calendar.

Example 1:



3. To complete column E, for class I and IIa products, use the code listed in the Implementing act 2017/2185 (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1563541170198&uri=CELEX:32017R2185) with a description of corresponding product in terms of clinical use.

4. To complete column E for class IIb product, used the official European nomenclature based on the Italian MD Nomenclature (http://www.salute.gov.it/imgs/C_17_pagineAree_328_listaFile_itemName_15_file.pdf).

5. For active class IIb conducting medicinal substances, for implantable Class IIb and for Class III product, you don't have to complete column E.

6. Column F must be completed for each class of device with the date at which your updated technical documentation will be available. The concerned technical documentation must be compliant with MDR (EU) 2017/745 requirements especially Annexes II and III.

   The given date in column F must be a date at which you are sure your documentation will be available for review. This date should be at least 1 year in advance of the expiry date of the current CE certificate and not later than 9 months in advance to allow you implementation of required corrective action if relevant after assessment by SGS's MD team.

7. Highlight in Yellow the date of technical documentation availability in each complete line to provide a global picture of your compliance planned date as per example 2 in following table.

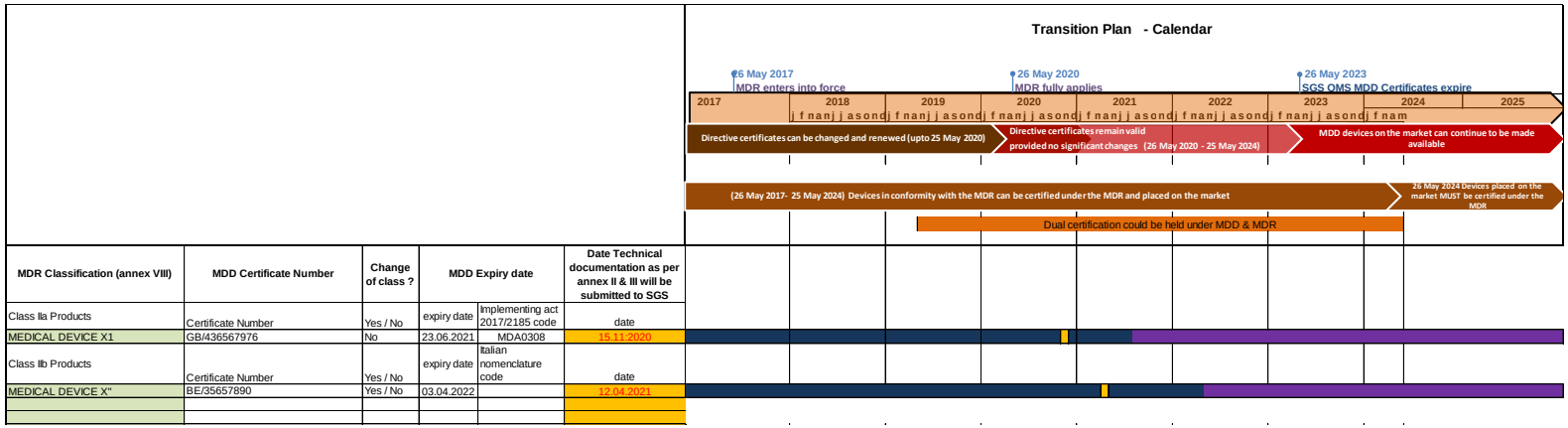
You will need to tell us when your technical files will be ready for assessment, as all the technical files that are covered by an MDR certificate must be updated under MDR. Remember that although we are sampling technical files, each one under a group or category must be updated and compliant with MDR.

Once you have listed all products of your existing portfolio that you want to transfer under MDR (EU) 2017/745 MD CE Certification and completed corresponding columns and calendar plan according to previous instructions, then please add into the table the list of products that you don't want to transfer using column F to state when you want to stop CE marking under MDD. You can decide to stop CE marking of the product at your convenience but before expiry date of the MDD CE certificate covering this product. Any line representing a product from the transition plan must be highlighted in the colour orange brown if the manufacturer wants to maintain both MDD and MDR certification till end of MDD CE certificate validity (see example 3).

Last part of the table corresponds to the list of new products that will need to certify directly under MDR. These are the product that are in your pipeline development for which you can provide us a date of technical documentation availability to let SGS plan the technical documentation review/examination in parallel of transfer of your current product portfolio. In the same way as for product that you are transferring, please complete date of technical documentation availability and transition plan calendar.

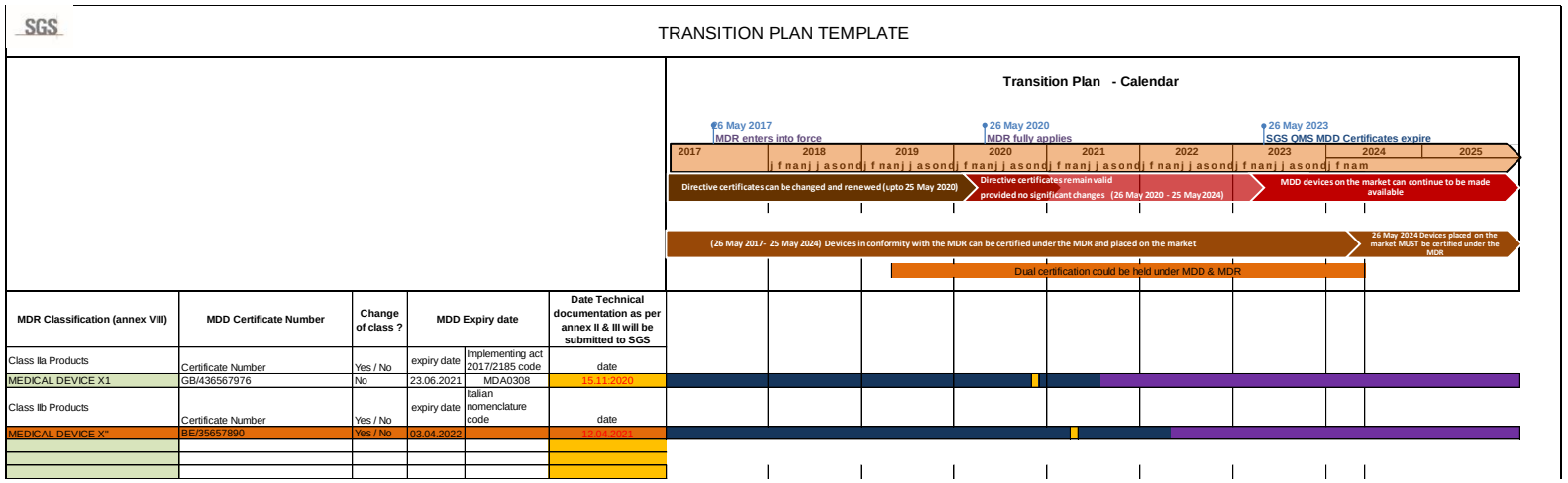
Once you have completed the transition plan, complete an "MDR Questionnaire" and send all your completed documents to your local SGS office (All the document's templates can be downloaded from our website: https://www.sgs.com/en/life-sciences/medical-devices/eu-medical-devices-regulations-information-center) as application forms.

Example 2: Completed Transition Plan - Calendar



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 IIa Products	Certificate Number	Yes / No	expiry date	Implementing act 2017/2185 code	date
MEDICAL DEVICE X1	GB/436567976	No	23.06.2021	MDA0308	15.11.2020
Class IIb Products	Certificate Number	Yes / No	expiry date	Italian nomenclature code	date
MEDICAL DEVICE X"	BE/35657890	Yes / No	03.04.2022		12.04.2021

Example 3: Complete Transition Plan with a product keeping MDD & MDR certification in parallel



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 IIa Products	Certificate Number	Yes / No	expiry date	Implementing act 2017/2185 code	date
MEDICAL DEVICE X1	GB/436567976	No	23.06.2021	MDA0308	15.11.2020
Class IIb Products	Certificate Number	Yes / No	expiry date	Italian nomenclature code	date
MEDICAL DEVICE X"	BE/35657890	Yes / No	03.04.2022		12.04.2021