

TRANSITION PLAN TEMPLATE

Tasks to complete your Transition Plan SGS:	Manufacturer's Name	Transition Plan - Calendar																											
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		<div style="display: flex; justify-content: space-between;"> 26 May 2017 MDR enters into force 26 May 2021 MDR fully applies 26 May 2024 SGS QMS MDD Certificates expire </div>																											
2. Identify any devices NOT being transitioned into MDR in the cells in this colour (row 50 onwards)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th>2017</th><th>2018</th><th>2019</th><th>2020</th><th>2021</th><th>2022</th><th>2023</th><th>2024</th><th>2025</th> </tr> <tr> <td style="text-align: center;">j f r a n j j a s o n d</td><td style="text-align: center;">j f r a n j j a s o n d</td><td style="text-align: center;">j f r a n j j a s o n d</td><td style="text-align: center;">j f r a n j j a s o n d</td><td style="text-align: center;">j f r a n j j a s o n d</td><td style="text-align: center;">j f r a n j j a s o n d</td><td style="text-align: center;">j f r a n j j a s o n d</td><td style="text-align: center;">j f r a n j j a s o n d</td><td style="text-align: center;">j f r a n j j a s o n d</td> </tr> </table>										2017	2018	2019	2020	2021	2022	2023	2024	2025	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d
2017	2018	2019	2020	2021	2022	2023	2024	2025																					
j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d	j f r a n j j a s o n d																					
3. Identify any new devices not currently certified por entering into MDR scope (e.g. Annex XVI devices)in the cells in this colour		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> Transition period (Dual certification could be held under MDD & MDR) </div>																											
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		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> Directive certificates can be changed and renewed (up to 25 May 2021) </div>																											
5. For Class Im, Is, Ir & Class IIa device, document Implementing act 2017/2185 code in column E		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> Directive certificates remain valid provided no significant changes (26 May 2021 - 25 May 2024) </div>																											
6. For class IIb devices, list italian nomenclature device group code in column E (row 30 onwards) if known		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> MDD only available on market </div>																											
7. List the MDD certificate expiry date for each device in column D		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> (26 May 2017- 25 May 2024) Devices in conformity with the MDR can be certified under the MDR and placed on the market </div>																											
8. For each device / device fill (in this colour) the calendar cells upto the expiry date (see example)		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> 26 May 2024 Devices placed on the market MUST be certified under the MDR </div>																											
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)		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> MDD only available on market </div>																											
10. Add the date when technical documentation is submitted into the calendar (see example)		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> MDD only available on market </div>																											
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		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> MDD only available on market </div>																											
12. For each device / device fill (in this colour)in your calendar dates after expiry of when you expect MDR certification		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> MDD only available on market </div>																											
13. Identify and fill (in this colour) any devices where Dual certification could be held in MDD & MDR		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> MDD only available on market </div>																											
14. Note:- SGS designation will depend on designation timescales outside of its control.		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> MDD only available on market </div>																											
15. note:- Once complete send a copy with your MDR application form (LPMREG1001) to your SGS local office		<div style="background-color: #f4cccc; padding: 5px; border: 1px solid black;"> MDD only available on market </div>																											

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	This yellow cell is marking the end of your CE certificate validity, move it according to your actual MDD certificate end of validity
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 certicates		N/A	Classification	Associated code if relevant	date	
Class Ir devices						
Annex XVI devices						
New device under development ...						

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 ...)