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Transition Timelines MDR 2017/745

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Content

1. Objective and Purpose

The Regulation 2017/745 on Medical Devices (MDR)[1] has become fully applicable on May 26, 2021. At the same time, the negotiations between Switzerland (CH) and the European Union (EU) on the Institutional Framework Agreement (InstA) were broken off and the amended Swiss Medical Device Ordinance (MedDO)[2] came into force.
Considering the current political situation, this document should help to keep an overview of the most important consequences, dates and deadlines.

2. Use Cases

In the illustration of the MDR transition periods, we outline use cases such as we frequently encounter in our daily practice with manufacturers and other economic operators.
The abbreviations we use in the tables are based primarily on practical experience and only secondarily on the regulatory definitions from the directives. These abbreviations are explained here.

Designation of use case	Explanation
Existing products	Medical devices that already have CE approval for the European market (i.e. conformity assessment) - also called "legacy products". This does not necessarily mean that these products must be physically located in a warehouse.
➢ With conformity assessment according to MDD	Placing on the market of medical devices for which a conformity assessment according to the old Directives 93/42/EEC or 90/385/EEC is given (excl. special case "type examination").
➢ Selling-off according to MDD	Making available on the market or putting into service of products already placed on the market in accordance with the MDD. These are finished products, which are e.g. in the warehouse of the distributor.
➢ Conformity assessment according to MDR	Placing on the market of medical devices for which a conformity assessment according to annex IX of the new Regulation (EU) 2017/745 MDR[1] is sought.
New products	Medical devices that do not yet have CE approval for the European market (i.e. no conformity assessment).
➢ Conformity assessment according to MDD	Medical devices for which conformity assessment and placing on the market is sought under the old Directives 93/42/EEC or 90/385/EEC (excl. special case "type examination").
➢ Conformity assessment according to MDR	Medical devices for which a conformity assessment and placing on the market according to Annex IX of the new regulation (EU) 2017/745 MDR[1] is sought.
Special case: higher classification	Extended transition periods apply to class I products that are newly assigned to a higher class according to the MDR. These are explained in section 6.2.

3. Medical Device Classes

Medical device class	Execution of the conformity assessment procedure according to annex IX, (EU) MDR 2017/745
I	By the manufacturer → self-declaration
Im / Ir / Is / IIa / IIb / III	With involvement of a notified body[a]

4. EUDAMED

The following timelines apply for new products as well as for legacy products[3]. The dates might be subject to change since they are based on the roadmap communicated by the Commission.

Requirements	Deadline
Launch of fully functional EUDAMED[4]	May 2022
6 months after full launch: company registration (MDR articles 29(4) and 56(5) are excluded)	November 2022
24 months after full launch: full registration[5]	May 2024

5. Situation between Switzerland and the European Union

Since Switzerland and the European Union have not yet been able to agree on a political solution, the economic operators must be prepared for drastic consequences. This was also made clear by the EU Commission with the "Notice to stakeholders: status of the agreement between the EU and Switzerland on the mutual recognition of medical devices"[6].
In addition, the amended Medical Devices Ordinance (MedDO)[2] leads to new obligations for manufacturers from the EU and other countries who want to place their products on the Swiss market.

5.1 Recognition of Certificates

ISO certificates such as for QM systems according to ISO 13485 remain valid.

	
For Swiss manufacturers placing their products on the EU market:	For EU manufacturers placing their products on the Swiss market:
Product certificates from notified bodies based in Switzerland are **no longer recognized** by the EU.	Product certificates are recognized by Switzerland.
Product certificates from notified bodies based in the EU are recognized by the EU, provided the Swiss manufacturer has established an authorized representative in the EU.	

[a] within the MedDO «Bezeichnete Stelle»

5.2 Appointment of Authorized Representatives

			
For Swiss manufacturers placing their products on the EU market, an **EU Representative** will be required from:		For EU manufacturers placing their products on the Swiss market, a **Swiss Representative** will be required from:	
May 26, 2021	all medical devices	July 31, 2022	Class I systems and procedure packs
		March 31, 2022	Class IIa / Class IIb non-implantable devices
		Dec 31, 2021	Class IIb / III implantable devices active implantable devices

5.3 Obligation to register and report to Swissmedic

Who	Requirements	Deadline
CH manufact.	Registration of the manufacturer (MedDO article 55).	within 3 months after placing on the market[b]
	Registration of economic operators who have already placed MDR-compliant medical devices on the Swiss market before May 26, 2021 (MedDO article 104b).	Nov 26, 2021
	Reporting of incidents by the manufacturer to Swissmedic (MedDO article 66).	deadlines acc. to MDR
NOT-CH manufact.	Designation of a Swiss importer (MedDO article 51).	within 3 months after placing on the market[b]
	Registration of manufacturer, Swiss authorized representative and Swiss importer with Swissmedic (MedDO article 55).	
	Registration of economic operators who have already placed MDR-compliant medical devices on the Swiss market before May 26, 2021 (MedDO article 104b).	Nov 26, 2021
	Appointment of a Swiss authorized representative (MedDO article 51).	chapter 5.2
	Reporting of incidents by the Swiss authorized representative to Swissmedic (MedDO article 66).	deadlines acc. to MDR

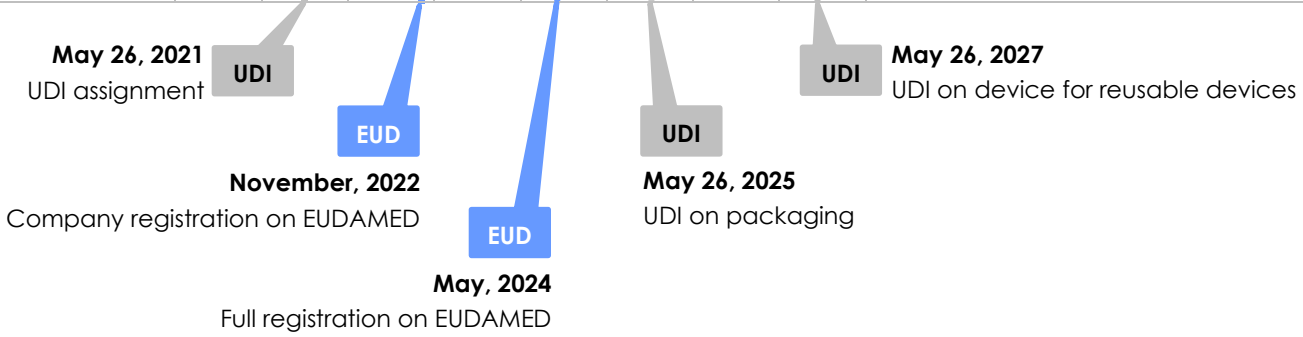
The requirements for persons who put together systems and procedure packs differ slightly from the requirements for manufacturers (MedDO articles 55 and 108).

[b] Refers to the first placing on the market after May 26, 2021.
Economic operators who only placed MDD products on the market before May 26, 2021 are exempt from registration.

6. Transition Periods according to Medical Device Classes

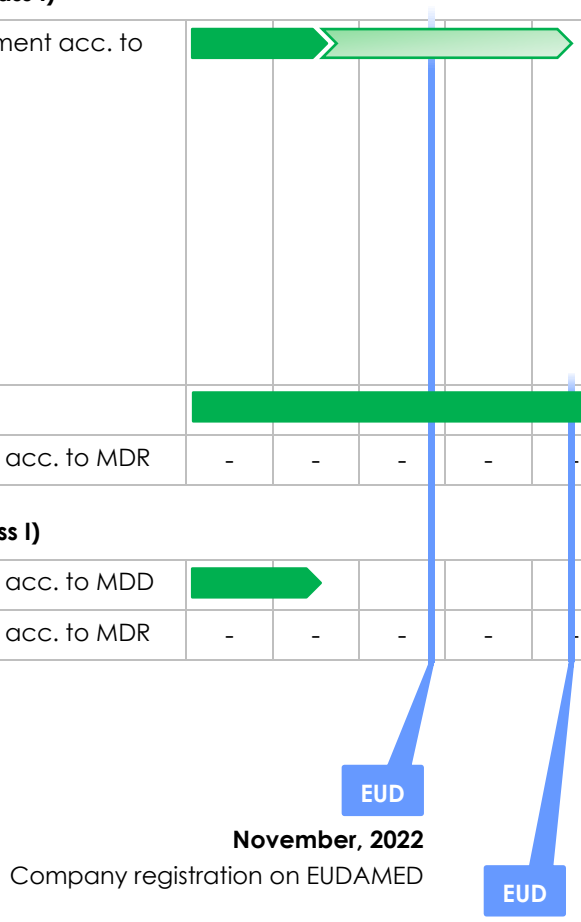
6.1 Class I (without Ir, Is, Im)

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product									
➢ With conformity assessment acc. to MDD									Possible until May 26, 2021, no extension for class I products
➢ Selling-off acc. to MDD									Possible until May 26, 2025
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021
New product									
➢ Conformity assessment acc. to MDD									Possible until May 26, 2021
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021



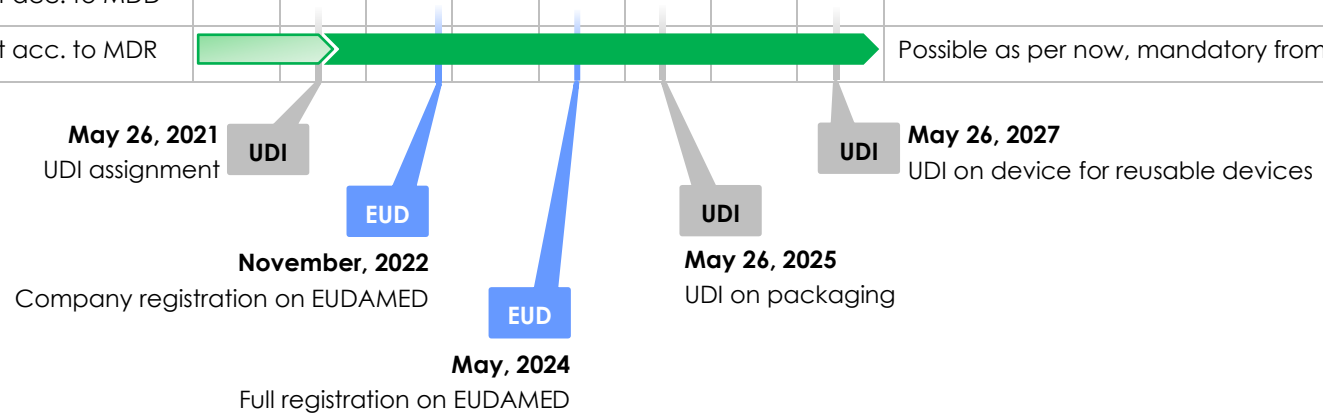
6.2 Special Case «Higher Classification of Class I»

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product (=MDD Class I)									
➢ With conformity assessment acc. to MDD									• Relevant is the expiry date of the existing declaration of conformity. To take advantage of the maximum transition period until May 26, 2024, the manufacturer's declaration of conformity must be renewed by May 26, 2021 at the latest • No significant changes[7] to the design and intended use are possible anymore • Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators and products must be fulfilled from May 26, 2021
➢ Selling-off acc. to MDD									Possible until May 26, 2025
➢ Conformity assessment acc. to MDR	-	-	-	-	-	-	-	-	See regulation for the new, higher class according to MDR
New product (=MDR > Class I)									
➢ Conformity assessment acc. to MDD									Possible until May 26, 2021 as class I acc. to MDD
➢ Conformity assessment acc. to MDR	-	-	-	-	-	-	-	-	See regulation for the new, higher class according to MDR



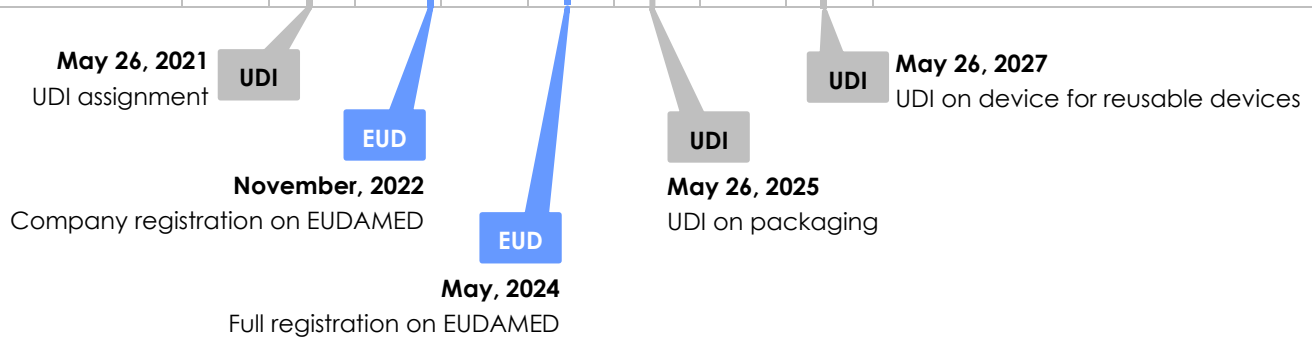
6.3 Class Ir

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product									
➢ With conformity assessment acc. to MDD	-	-	-	-	-	-	-	-	
➢ Selling-off acc. to MDD	-	-	-	-	-	-	-	-	This is a new class of medical devices in the MDR. → For details see descriptions under par. 6.2
➢ Conformity assessment acc. to MDR	-	-	-	-	-	-	-	-	
New product									
➢ Conformity assessment acc. to MDD	-	-	-	-	-	-	-	-	
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021



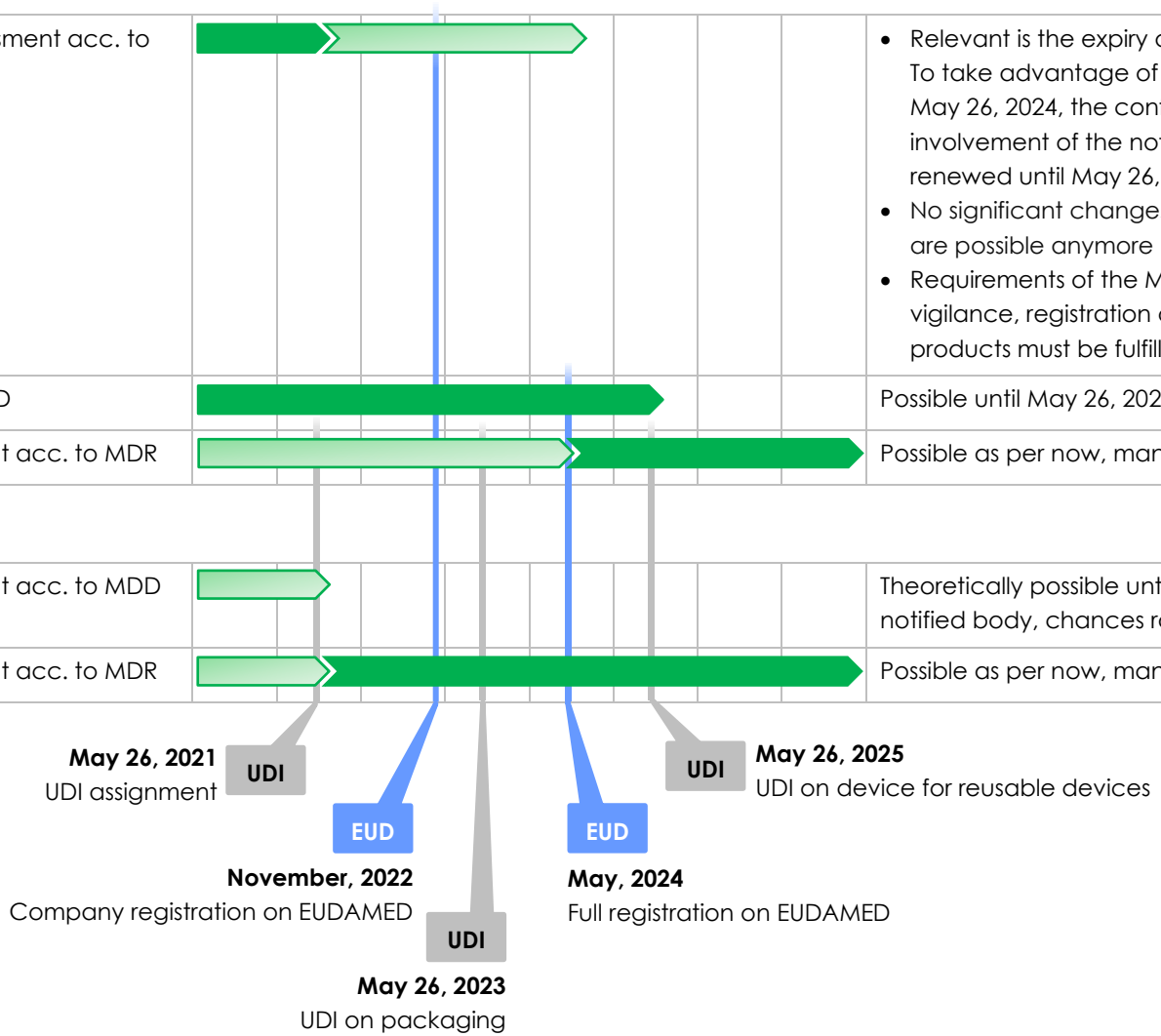
6.4 Class Is, Im

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product									
➢ With conformity assessment acc. to MDD									• Relevant is the expiry date of the existing EC certificate. To take advantage of the maximum transition period until May 26, 2024, the conformity assessment with the involvement of the notified body may have to be renewed until May 26, 2021 at the latest. • No significant changes[7] to the design and intended use are possible anymore • Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators and products must be fulfilled from May 26, 2021
➢ Selling-off acc. to MDD									Possible until May 26, 2025
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2024
New product									
➢ Conformity assessment acc. to MDD									Theoretically possible until May 26, 2021, depending on the notified body, chances rather low
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021



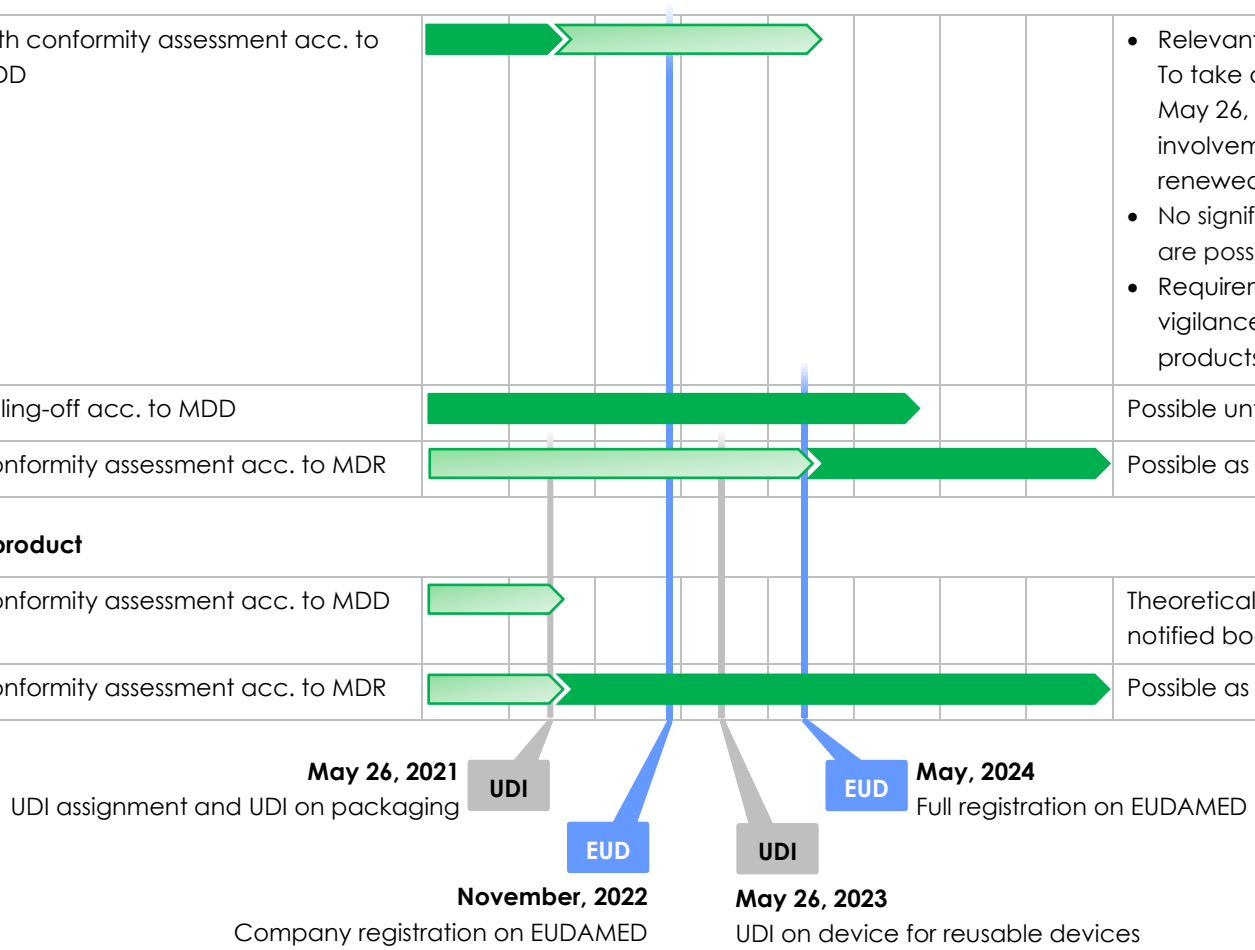
6.5 Class IIa and IIb (non-implantable)

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product									
➢ With conformity assessment acc. to MDD									• Relevant is the expiry date of the existing EC certificate. To take advantage of the maximum transition period until May 26, 2024, the conformity assessment with the involvement of the notified body may have to be renewed until May 26, 2021 at the latest. • No significant changes[7] to the design and intended use are possible anymore • Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators and products must be fulfilled from May 26, 2021
➢ Selling-off acc. to MDD									Possible until May 26, 2025
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2024
New product									
➢ Conformity assessment acc. to MDD									Theoretically possible until May 26, 2021, depending on the notified body, chances rather low
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021



6.6 Class IIb (implantable) and Class III

Use Cases	2020	2021	2022	2023	2024	2025	2026	2027 >>	Comments
Existing product									
➢ With conformity assessment acc. to MDD									• Relevant is the expiry date of the existing EC certificate. To take advantage of the maximum transition period until May 26, 2024, the conformity assessment with the involvement of the notified body may have to be renewed until May 26, 2021 at the latest. • No significant changes[7] to the design and intended use are possible anymore • Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators and products must be fulfilled from May 26, 2021
➢ Selling-off acc. to MDD									Possible until May 26, 2025
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2024
New product									
➢ Conformity assessment acc. to MDD									Theoretically possible until May 26, 2021, depending on the notified body, chances rather low
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from May 26, 2021



7. Bibliography / References

No. in the present document	Literature	Hyperlink
1	**Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices Last modification: April 24, 2020	Link
2	**Swiss Medical Device Ordinance (MedDO)** Last modification: May 19, 2021	Link
3	**MDCG 2019-5** Registration of legacy devices in EUDAMED Last modification: April 15, 2019	Link
4	**MDCG 2021-1 Rev.1** Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional Last modification: May 2021	Link
5	**MDCG 2019-4** Timelines for registration of device data elements in EUDAMED Last modification: April 15, 2019	Link
6	**Notice to stakeholders**: status of the EU-Switzerland Mutual Recognition Agreement (MRA) for medical devices Last modification: May 26, 2021	Link
7	**MDCG 2019-3** Interpretation of article 54(2)b rev. 1 Medical Device Coordination Group about Significant changes Last modification: April 6, 2021	Link

8. Our Experience - Your Benefit

We at inmedis are the experts for quality management and regulatory affairs in medical technology. With our well-founded know-how and the neutral view of the external consultant we guarantee a successful project completion. I look forward to hearing from you.

Kind regards

inmedis GmbH

Gerhard Dariz
Managing Director