Transition Timelines MDR 2017/745

as of October 15, 2023

Author: inmedis GmbH
Published: 23.11.2023
Version: 8.0

Content

1. Objective and Purpose

The Regulation 2017/745 on Medical Devices (MDR)[1] has become fully applicable on May 26, 2021. With the amendment of the regulation as of 20 March 2023[8], longer transitional periods apply to existing MDD certificates ("legacy devices"). This document is intended to help you keep an overview of the most important consequences and dates of the MDR.
For the current situation in Switzerland due to the updated Medical Devices Ordinance (MedDO) we refer to the inmedis-document "Transition periods MedDO"[2].

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 current 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 current 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 5.2.

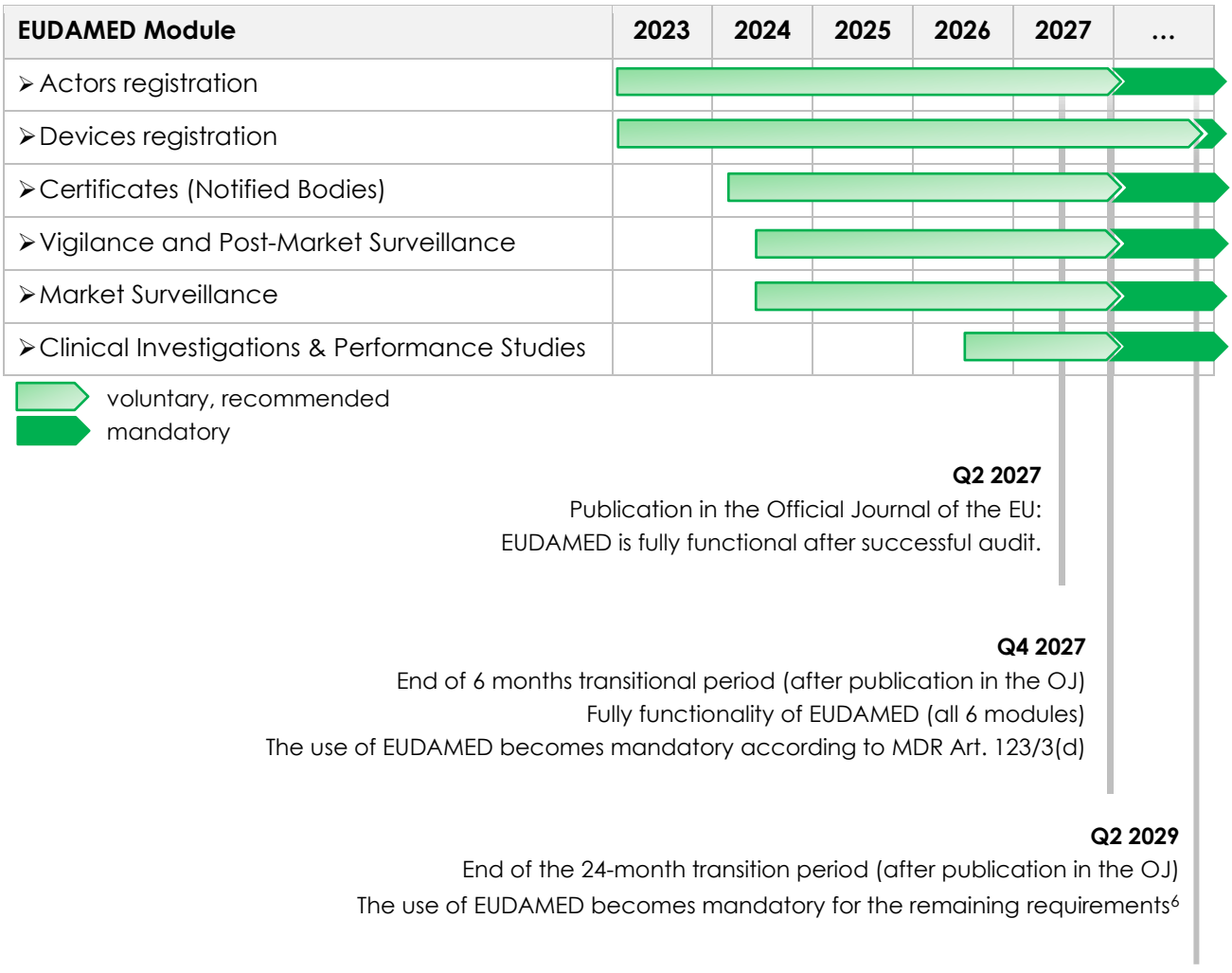
3. Medical Device Classes

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

4. EUDAMED

The EUDAMED database will consist of six modules, with the first three modules currently being available. The available modules should already be used on a voluntary basis or according to country-specific requirements for data collection[4].

The following deadlines apply for new products as well as for "legacy products"[3] which are placed on the EU market. The dates might be subject to change since they are based on the roadmap[5] communicated by the Commission.

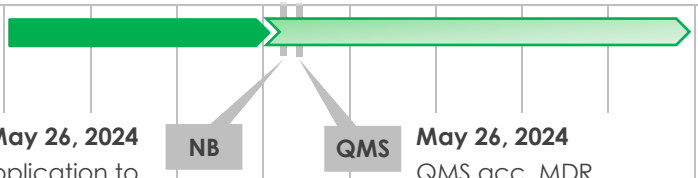


5. Transition Periods according to Medical Device Classes

5.1 Class I (without Ir, Is, Im)

Use Cases	2021	2022	2023	2024	2025	2026	2027	2028	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									The sales deadline from the previously valid MDR 2017/745 is no longer applicable. Products placed on the market according to MDD can now be sold without restriction within the shelf life - even beyond Dec. 2028
➢ Conformity assessment acc. to MDR									Mandatory since May 26, 2021
New product									
➢ Conformity assessment acc. to MDD									Possible until May 26, 2021
➢ Conformity assessment acc. to MDR									Mandatory since May 26, 2021

5.2 Special Case «Higher Classification of Class I»

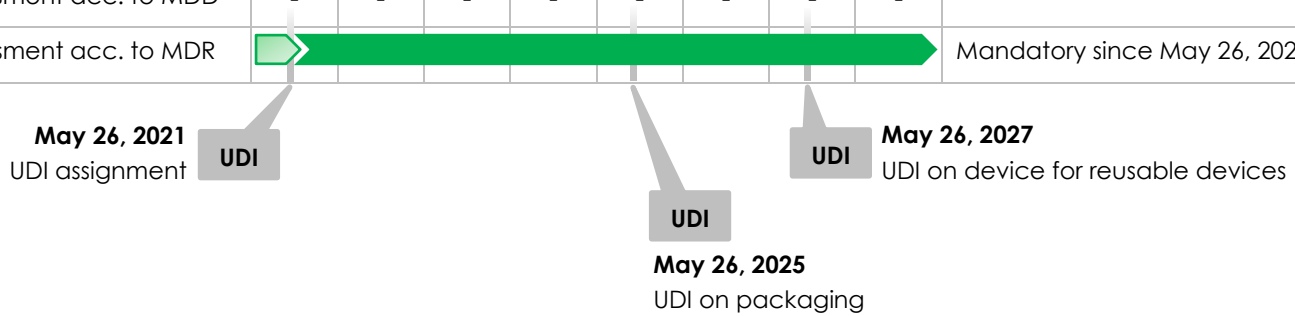
Use Cases	2021	2022	2023	2024	2025	2026	2027	2028	Comments
Existing product (=MDD Class I)									
➢ Manufacturer must have renewed the MDD Declaration of Conformity before May 26, 2021									Conditions see *
➢ Selling-off acc. to MDD									The sales deadline from the previously valid MDR 2017/745 is no longer applicable. Products placed on the market according to MDD can now be sold without restriction within the shelf life - even beyond Dec. 2028
➢ 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

** Conditions

- No significant changes[7] of the design and intended use possible.
- Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators, and products must be met from 26 May 2021.
- The products continue to comply with Directive 90/385/EEC or Directive 93/42/EEC.
- The products do not pose an unacceptable risk to the health or safety of patients, users, or any other person or to any other aspect of public health protection.
- The manufacturer must have established a quality assurance system in accordance with MDR requirements by 26 May 2024 at the latest.
- The manufacturer or an authorised representative must submit a formal application for MDR certification to the notified body by 26 May 2024 at the latest; by 26 September 2024 at the latest, the notified body and the manufacturer must have signed a written agreement.

5.3 Class Ir

Use Cases	2021	2022	2023	2024	2025	2026	2027	2028	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. 5.2
➢ Conformity assessment acc. to MDR	-	-	-	-	-	-	-	-	
New product									
➢ Conformity assessment acc. to MDD	-	-	-	-	-	-	-	-	
➢ Conformity assessment acc. to MDR									Mandatory since May 26, 2021



5.4 Class Is, Im

Use Cases	2021	2022	2023	2024	2025	2026	2027	2028	Comments
Existing product									
Case a: Validity of the MDD declaration ends before 20 March 2023 and prerequisites * are not fulfilled									Products must not be placed on the market
Case b: Validity of the MDD declaration ends before 20 March 2023 and prerequisites * are fulfilled									Conditions see **
Case c: Validity of the MDD declaration longer than 20 March 2023 and prerequisites * are fulfilled									Conditions see **
➢ Selling-off acc. to MDD									The sales deadline from the previously valid MDR 2017/745 is no longer applicable. Products placed on the market according to MDD can now be sold without restriction within the shelf life - even beyond Dec. 2028
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from January 01, 2029
New product									
➢ Conformity assessment acc. to MDD									Possible until May 26, 2021
➢ Conformity assessment acc. to MDR									Mandatory since May 26, 2021

May 26, 2024
MDR-application to the Notified Body

NB

QMS

May 26, 2024
QMS acc. MDR

UDI
May 26, 2021
UDI assignment

UDI
May 26, 2025
UDI on packaging

UDI
May 26, 2027
UDI on device for reusable devices

Legend:

*Prerequisites

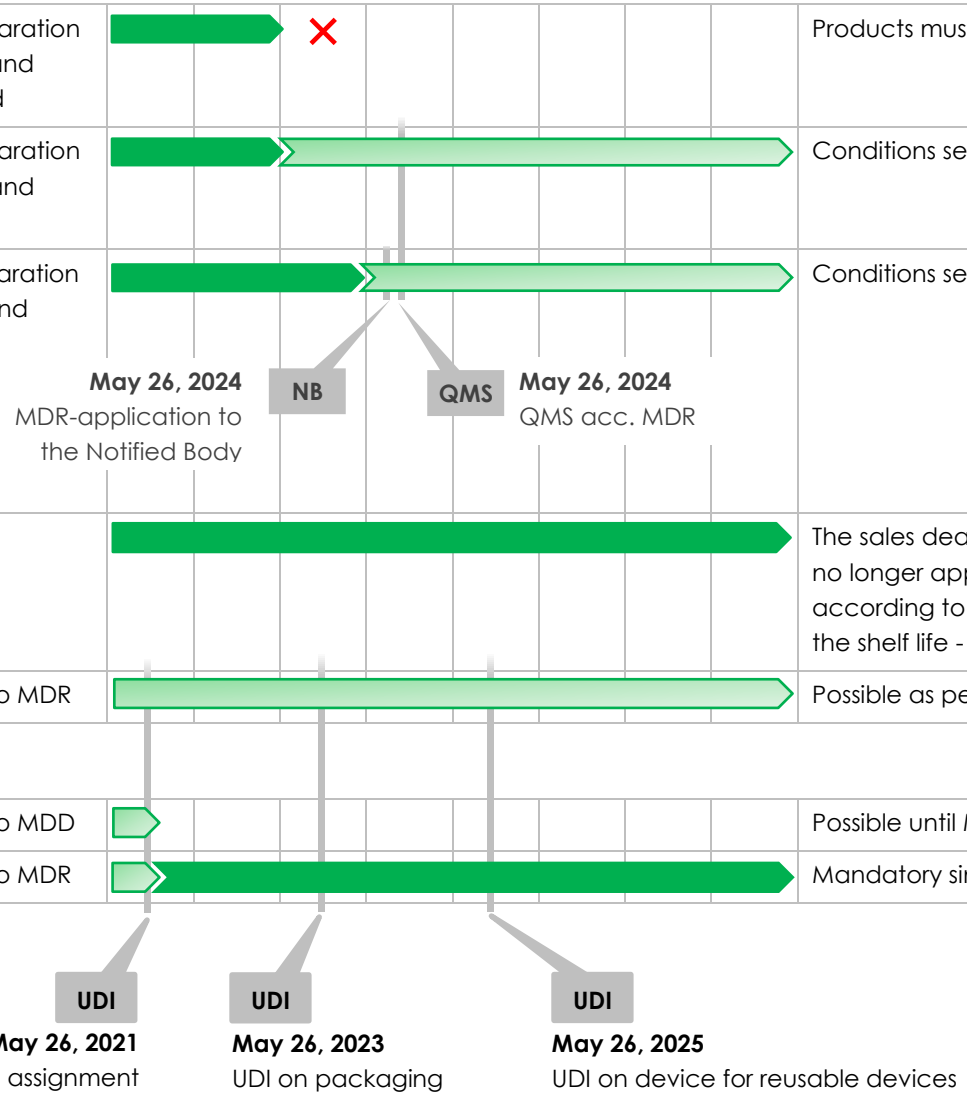
- Certificates that expired before 20 March 2023 shall only be considered valid until 31 December 2028 if one of the following conditions is met:
  a) before the expiry of the certificate, the manufacturer and a notified body have signed a written agreement for conformity assessment in relation to the product for which the certificate has expired or to a device intended to replace that device.
  b) a competent authority of a Member State has granted a derogation (in accordance with Article 59 or Article 97)

** Conditions

- No significant changes[7] of the design and intended use possible.
- Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators and products must be met since 26 May 2021.
- The products continue to comply with Directive 90/385/EEC or Directive 93/42/EEC.
- The products do not pose an unacceptable risk to the health or safety of patients, users, or any other person or to any other aspect of public health protection.
- The manufacturer must have established a quality assurance system in accordance with MDR requirements by 26 May 2024 at the latest.
- The manufacturer or an authorised representative must submit a formal application for MDR certification to the notified body by 26 May 2024 at the latest; by 26 September 2024 at the latest, the notified body and the manufacturer must have signed a written agreement.

5.5 Class IIa and IIb (non-implantable)

Use Cases	2021	2022	2023	2024	2025	2026	2027	2028	Comments
Existing product									
Case a: Validity of the MDD declaration ends before 20 March 2023 and prerequisites * are not fulfilled			✕						Products must not be placed on the market
Case b: Validity of the MDD declaration ends before 20 March 2023 and prerequisites * are fulfilled									Conditions see **
Case c: Validity of the MDD declaration longer than 20 March 2023 and prerequisites * are fulfilled									Conditions see **
➢ Selling-off acc. to MDD									The sales deadline from the previously valid MDR 2017/745 is no longer applicable. Products placed on the market according to MDD can now be sold without restriction within the shelf life - even beyond Dec. 2028
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from January 01, 2029
New product									
➢ Conformity assessment acc. to MDD									Possible until May 26, 2021
➢ Conformity assessment acc. to MDR									Mandatory since May 26, 2021



Legend:

*Prerequisites

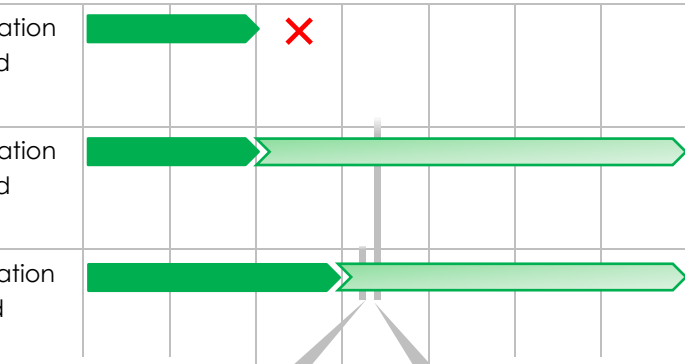
- Certificates that expired before 20 March 2023 shall only be considered valid until 31 December 2028 if one of the following conditions is met:
  a) before the expiry of the certificate, the manufacturer and a notified body have signed a written agreement for conformity assessment in relation to the product for which the certificate has expired or to a device intended to replace that device.
  b) a competent authority of a Member State has granted a derogation (in accordance with Article 59 or Article 97)

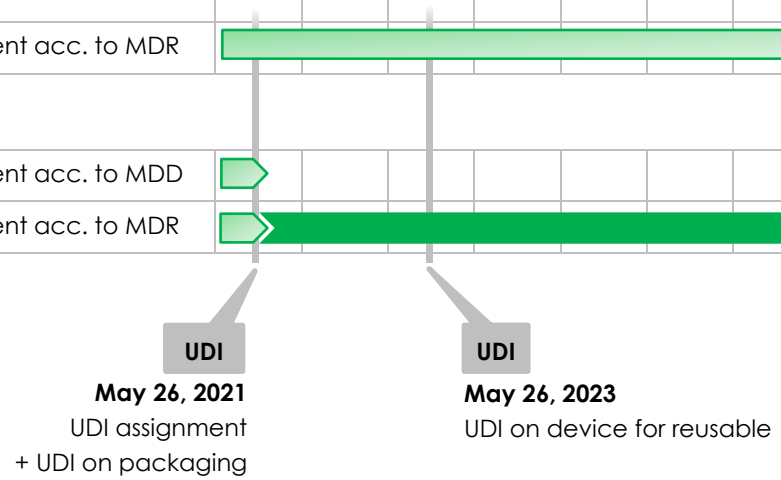
** Conditions

- No significant changes[7] of the design and intended use possible.
- Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators and products must be met since 26 May 2021.
- The products continue to comply with Directive 90/385/EEC or Directive 93/42/EEC.
- The products do not pose an unacceptable risk to the health or safety of patients, users, or any other person or to any other aspect of public health protection.
- The manufacturer must have established a quality assurance system in accordance with MDR requirements by 26 May 2024 at the latest.
- The manufacturer or an authorised representative must submit a formal application for MDR certification to the notified body by 26 May 2024 at the latest; by 26 September 2024 at the latest, the notified body and the manufacturer must have signed a written agreement.

5.6 Class IIb (implantable*) and Class III

Use Cases	2021	2022	2023	2024	2025	2026	2027	2028	Comments
Existing product									
Case a: Validity of the MDD declaration ends before 20 March 2023 and prerequisites** are not fulfilled									Products must not be placed on the market
Case b: Validity of the MDD declaration ends before 20 March 2023 and prerequisites** are fulfilled									Conditions see ***
Case c: Validity of the MDD declaration longer than 20 March 2023 and prerequisites** are fulfilled									Conditions see ***
➢ Selling-off acc. to MDD									The sales deadline from the previously valid MDR 2017/745 is no longer applicable. Products placed on the market according to MDD can now be sold without restriction within the shelf life - even beyond Dec. 2027
➢ Conformity assessment acc. to MDR									Possible as per now, mandatory from January 01, 2028
New product									
➢ Conformity assessment acc. to MDD									Possible until May 26, 2021
➢ Conformity assessment acc. to MDR									Mandatory since May 26, 2021





Legend:

* except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

**Prerequisites

- Certificates that expired before 20 March 2023 shall only be considered valid until 31 December 2027 if one of the following conditions is met:
  a) before the expiry of the validity of the certificate, the manufacturer and a notified body have signed a written agreement for conformity assessment in relation to the product for which the certificate has expired or to a device intended to replace that device.
  b) a competent authority of a Member State has granted a derogation (in accordance with Article 59 or Article 97)

*** Conditions

- No significant changes[7] of the design and intended use possible.
- Requirements of the MDR for post-market surveillance, vigilance, registration of economic operators and products must be met since 26 May 2021.
- The products continue to comply with Directive 90/385/EEC or Directive 93/42/EEC.
- The products do not pose an unacceptable risk to the health or safety of patients, users, or any other person or to any other aspect of public health protection.
- The manufacturer must have established a quality assurance system in accordance with MDR requirements by 26 May 2024 at the latest.
- The manufacturer or an authorised representative must submit a formal application for MDR certification to the notified body by 26 May 2024 at the latest; by 26 September 2024 at the latest, the notified body and the manufacturer must have signed a written agreement.

6. 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	**Transition Timelines MedDO** Last modification: August 11, 2022	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	**EUDAMED Roadmap** published by the European Commission Last modification: October 2023	Link
6	**MDCG 2019-4** Timelines for registration of device data elements in EUDAMED Last modification: April 15, 2019	Link
7	**MDCG 2020-3** Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD Last modification: March 2020	Link
8	**Regulation (EU) 2023/607** of the European Parliament and the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices. Last modification: March 2023	Link

7. 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