Dear Sir or Madam,

Today we would like to provide further information on the following topics:

1 BFARM - NOTIFICATION PORTAL FOR NON-INTERVENTIONAL STUDIES (ANWENDUNGSBEOBACHTUNG - AWB) AND OF NON-INTERVENTIONAL POST-AUTHORISATION SAFETY STUDIES (PASS) 2
2 LEGACY DEVICES – NECESSITY FOR FORMAL APPLICATION FOR NOTIFIFIED BODY CONFORMITY ASSESSMENT UNTIL 26 MAY 2024 2

We are at your disposal, should you require assistance or have further questions.

Best regards

The DiaMed Team

1 BFARM - NOTIFICATION PORTAL FOR NON-INTERVENTIONAL STUDIES (ANWENDUNGSBEOBACHTUNG - AWB) AND OF NON-INTERVENTIONAL POST-AUTHORISATION SAFETY STUDIES (PASS)

The Federal Institute for Drugs and Medical Devices (BfArM) has launched a new notification portal for the notification of observational studies (Anwendungsbeobachtungen (AWB)) and non-interventional safety studies (PASS), which can be accessed at https://awbdb.bfarm.de/ords/r/awb/awb_pub/home.

The notification portal replaces the previous procedure, in which notifications were sent by email to awb@bfarm.de or pass@bfarm.de using a pdf form provided by the BfArM.

Notifications by e-mail are therefore no longer possible.

2 LEGACY DEVICES – NECESSITY FOR FORMAL APPLICATION FOR NOTIFIED BODY CONFORMITY ASSESSMENT BY 26 MAY 2024

An important deadline for medical devices is fast approaching: 26 May 2024. It affects manufacturers of medical devices that are considered legacy devices. These are Class I medical devices according to MDD (93/42/EEC) with a declaration of conformity issued before 26 May 2021 that require a conformity assessment procedure by a notified body under the MDR (Regulation (EU) 2017/745) or medical devices with an EC certificate according to MDD issued before 26 May 2021.

For these medical devices, Article 120 of the MDR on transitional provisions applies and the medical devices may be placed on the market until 31 December 2027 or 31 December 2028 under certain conditions. The conditions are:

Condition	Deadline
Putting in place a QMS pursuant to Art. 10(9) MDR	No later than 26 May 2024
Lodging an application for conformity assessment procedure of the device or a substitute device pursuant to Annex VII, Section 4.3, 1st subparagraph in accordance with Article 52 MDR (by the manufacturer or authorised representative)	No later than 26 May 2024
Conclusion of a written agreement for conformity assessment in accordance with Annex VII, Section 4.3, 2nd subparagraph, MDR in respect of the legacy device or a substitute device between manufacturer and notified body	No later than 26 September 2024

We would like to draw your attention to these helpful documents from the European Commission, which provide further support on how to proceed:

Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic REV. 1

Conditions and deadlines for placing ‘legacy devices’ and class III custom-made implantable devices on the market or putting them into service in accordance with Article 120 MDR, as amended by Regulation 2023/607 Flowchart Rev. 1 (this document also contains additional information on the term “substitute”)