

ATTESTATION
STATEMENT

Réf : FQ308A
Date : 03/01/22

Statement number: FQ308-REG-07/06/2024-Ila & Ilb –Confirmation letter & CE Certificate

Department: Regulatory

Subject: Explanation on notified body confirmation letter and CE certificate to be used for
Laboratories Anios & D.M.D

Revision History:

Revision number	Date	Scope
01	07/06/2024	Initial release following new notified body confirmation letter

Lezennes, 07/06/2024

The purpose of this statement is to explain the context of the notified body confirmation letters received for Laboratories Anios & D.M.D, as well as the relationship with current CE Certificates which have been extended. The following points are to be taken into consideration for current CE Certification of Anios & D.M.D:

Extension of CE Certificate expiry date:

In regards of regulation 2023/607 the notified body confirmation letter respectively for Anios and D.MD, n°1000172972 and n° 1000178267 set the extension of expiry date for the CE Certificates to the date of 31/12/2028 (as indicated for Class Ila & Ilb medical devices). Therefore for current CE certification, the CE Certificates n°31390 rev.21 (Anios) and n°31393 rev.14 (D.M.D) and their confirmation letter need to be used.

Change of notified body:

Additionally, the notified body confirmation letters were issued by the notified body DQS as for the transition towards medical device regulation EU 2017/745 (MDR), both entities Anios & D.M.D are switching from GMED to DQS. Thereby, DQS is taking over the surveillance of previous CE marked products which are listed in the confirmation letter and CE Certificates. Due to this change, new Declarations of conformity have been issued with DQS as notified body.

Medical device class to be considered during transition period:

The confirmation letters indicate the expected medical device classification to be applied under MDR certification. In regard to this, when comparing the classification indicated in the CE Certificates n°31390 rev.21 (Anios) and n°31393 rev.14 (D.M.D) some products are intended to switch from Ilb classification to Ila classification; This is due to the fact that under MDR, other classification rules will apply which leads to reclassifications for some products. In the meantime, until MDR Certification is obtained, the risk classification of medical devices to be considered is the one from the current CE Certificates n°31390 rev.21 (Anios) and n°31393 rev.14 (D.M.D).

Products not included in the notified body confirmation letter:

Products which were previous listed in the CE Certificates n°31390 rev.21 (Anios) and n°31393 rev.14 (D.M.D) but do not appear in the confirmation's letters are to be considered as phased out. Additional statement is provided on this topic for phased out products.

Collecté par : Author

Durée : Illimité

Lieu d'archivage : Dans la FO/MOC/TF correspondant

Responsable d'archivage : Approbateur

Classement & Indexage : FQ308-REG-07/06/2024-Ila & Ilb –Confirmation letter & CE Certificate

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Signatures:

Name	Function	Role	Date + Signature
Nicolas Mascaro	Regulatory affairs specialist	Author	 Digitally signed by Mascaro Nicolas Date: 2024.06.07 14:53:03 +02'00'

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