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Date July 07, 2021

Application for : QMS
Certificate No. : HD 60146428 0001
Requirement : MDD Annex II excl. 4
Confirmation letter ID : DOC_2021-07-07_ HD 60146428 0001
Report no. : 1087480-20

Dear Mr. Jens Schmidt,

**Update of information to
Certificate no. HD 60146428 0001, issued on 2020-04-02**

The significant change notification received on 2021-04-22 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.

We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the above mentioned certificate:

The manufacturer's legal entity is changed from Löwenstein Medical GmbH & Co. KG to **Löwenstein Medical SE & Co. KG**.

The scope of the HD 60146428 0001 certificate remains the same:
Medical devices for anesthesia, intensive care, neonatology, phototherapy, homecare, sleep diagnostic and pulmonology.

Best regards,



Signiert von: Daniele Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
Certification body

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