

INJEX Pharma GmbH
Haynauer Straße 72A
12249 Berlin
Germany

2025-11-24

Notified Body Confirmation Letter

Reference: 544966 MR2

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework 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 medical device

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

INJEX Pharma GmbH
Haynauer Straße 72A
12249 Berlin
Germany
SRN: DE-MF-000006766

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but

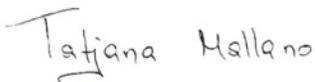
DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,



Dr. Tatjana Mallano
Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device family: Injector Device name: Injex30 Basic UDI-DI: DE-MF-000006766-338011001	Class IIb excluding Class IIb implantable non-WET	N/A	MDD EC-Certificate, Reference: 544966 MR2, unique ID-No.: 170775961, issued by DQS (NB 0297) on 13 May 2021
Device family: Ampulle Device name: Injex Ampulle U-100 Basic UDI-DI: DE-MF-000006766-546000400	Class I devices placed on the market in sterile condition; Class I devices with a measuring function	N/A	MDD EC-Certificate, Reference: 544966 MR2, unique ID-No.: 170775961, issued by DQS (NB 0297) on 13 May 2021
Device family: Adapter Device name and Basic UDI-DI: Injex Vial 14-Adapter, DE-MF-000006766-511000400 Injex Vial 22-Adapter, DE-MF-000006766-511000800 Injex Transporter-Adapter, DE-MF-000006766-511000700 Injex Pen-Adapter, DE-MF-000006766-511000500 Injex Luer-Adapter, DE-MF-000006766-511000600	Class I devices placed on the market in sterile condition	N/A	MDD EC-Certificate, Reference: 544966 MR2, unique ID-No.: 170775961, issued by DQS (NB 0297) on 13 May 2021

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2021-04-17	DQS reference: 544966 MR2, Certificate unique ID-No.: 170774330	Initial issue of EC-Certificate by DQS
2021-05-13	DQS reference: 544966 MR2, Certificate unique ID-No.: 170775961	Addition of Device of Injex Ampoul U-100, Injex Vial 14-Adapter, Injex Vial 22-Adapter, Injex Transporter-Adapter, Injex Pen-Adapter and Injex Luer-Adapter