EC Certificate Full Quality Assurance System: Certificate
Certificat CE Système complet d'assurance de qualité :
FR19/81843446

The management system of / Le système de management de

MDJ sas

ZI Racine Palladuc, 63650 La Monnerie Le Montel, France

has been assessed and certified as meeting the requirements of / a été audité et certifié selon les exigences de

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)
on medical devices, Annexe II (section 4 exclue)

For the following products / Pour les produits suivants

The scope of registration appears on page 2 of this certificate.
La domaine de certification apparaîtenpage 2 de ce certificat.

This certificate is valid from 16 December 2019 until 31 August 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 01 September 2003
and first certified by SGS Belgium NV since 16 December 2019

Ce certificat est valable du 16 décembre 2019 au 31 août 2023
et reste valide sous condition d'audits de surveillance satisfaisants.
Version 1. Certifié depuis 01 septembre 2003
et initialement certifié par SGS Belgium NV depuis 16 décembre 2019

Certification is based on reports numbered / La certification est basée sur les rapports référence FR/MD 209213

Authorised by / Autorisé par

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

MDJ sas

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)
on medical devices, Annexe II (section 4 exclue)

Issue / Version 1

For the following products / Pour les produits suivants

Single use sets with sterile injector, cartridge and pusher for injection of intraocular lenses (IOL).

Sets stériles à usage unique composés de: injecteur, cartouche, et poussoir, pour l'injection de lentilles intra-oculaires.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Lorsque le champ d'application ci-dessus comprend un ou plusieurs dispositifs médicaux de classe III, un certificat EC Design Examination Certificate valide, conformément à l'annexe II (section 4), est obligatoire pour chaque dispositif, en addition du présent certificat, pour la mise sur le marché du dispositif.

MDJ sas
ZI Racine Palladuc,
63650 La Monnerie Le Montel, France

April 6 2023

Confirmation Letter Reference: CLNB1639 – FR/MD237804

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement 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 devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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

MDJ sas
ZI Racine Palladuc,
63650 La Monnerie Le Montel, France
SRN Number : FR41 409 060 100

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices

- 31st 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)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st 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 SGS Belgium NV 1639,

Ian How
PP

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI	**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
IOL Injection sytem: CartInject® and LoadInject® 376034321IOLINJECT	Class IIa	Single use sets with sterile injector, cartridge and pusher for injection of intraocular lenses (IOL)	FR19/81843446 NB 1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/06/22	Version 1	Initial issue