NOTICE BELGELENDIRME CONFIRMATION LETTER

Notice Belgelendirme Muayene ve Denetim Hizmetleri A.S.

Esentepe Mah. Milangaz Cad. Manumento Plaza No: 75/A/92 Kartal / Istanbul / Turkiye
e-mail: info@notice.com.tr // Phone: +90 (216) 504 16 98

<2024.03.19>

Reference: CF-2764-MT-013.V0

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.

This letter indicates that NOTICE, a Notified Body (NB) designated in accordance with (EU) 2017/745 MDR Regulation and numbered 2764 in NANDO, has received a formal application in accordance with the first subparagraph of MDR Annex VII Part 4.3 and confirms that it has signed a written agreement in accordance with the second subparagraph of MDR Annex VII Part 4.3 with the following manufacturer:

Company Name	:	JETEMA Co., Ltd.
Company Address	:	16-25, Dongbaekjungang-ro 16beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea
Country	:	Republic of Korea
SRN Number	:	KR-MF-000029861

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NOTICE BELGELENDIRME is also responsible for appropriate surveillance of the corresponding devices under the 93/42/EEC Medical Device Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

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- 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 Notice Belgelendirme Muayene ve Denetim Hizmetleri A.S.,

Özlem VİCDAN AKDAĞ
Chairman

Table 1: Devices covered by this letter and for which the NOTICE BELGELENDIRME is also responsible for appropriate surveillance of the corresponding devices under the 93/42/EEC Medical Device Directive

Device name or Basic UDI-DI (under MDR 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Implant, Hyaluronic Acid Gel **UDI-DI: 88000212e.p.t.q.001QF**	Class III	--	CE-MDD-0106/02/2020/01-rev.02 (NB:2764) CE-MDD-0106/02/2020/01/DD.01-rev.02 (NB:2764)
Models:			
e.p.t.q • S500 • S300 • S100			
REGENOUVE • Sub-Q • Deep • Fine			
IRI • S600 • S400 • S200			
STARFILL • Implant Plus • Deep Plus • Plus			

Device name or Basic UDI-DI (under MDR 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Implant, Hyaluronic acid gel With Lidocaine **UDI-DI: 88000212e.p.t.q.L001QT**	Class III	--	CE-MDD-0021/01/2020/01 Rev.02 (NB:2764) CE-MDD-0021/01/2020/01/DD.01 Rev.02 (NB:2764)
Models:			
e.p.t.q Lidocaine • S500 • S300 • S100			
REGENOVUE • Sub-Q Plus • Deep Plus • Fine Plus			
PHILLEX • Sub-Q Plus • Deep Plus • Fine Lips			
STARFILL • Implant Plus Lidocaine • Deep Plus Lidocaine • Plus Lidocaine			
ELOQUENCE • Sub-Q • Deep • Fine			
INTRALINE • M4 Plus • M3 Plus • M2 Plus			
VOLONIC • Intense Lidocaine • Mild Lidocaine • Light Lidocaine			

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Confirmation Letter Revision History

Date	Relevant Version No	Action
2024.03.19	CF-2764-MT-013.V0	First Issue