DECLARATION OF ACCEPTANCE OF THE VARIATION TO THE TECHNICAL FILE

EC certification nr.	**0068/QCO-DM/213-2020**
Validity	**27/05/2024**
Manufacturer	**JSKBiomed Inc.** #509, 272-16, Munji-ro, Yuseong-gu, Daejeon, Republic of Korea
Conformity procedure	**Annex II – 93/42/EEC directive and amendments**
Medical device/s	**Sterile, single use needle free injector + connector and handpieces** *Brand name:* **Mirajet nozzle** *Models:* **MJNZ-1H150; MJNZ-1H200; MJNZ-1H250;** **Handpieces** *Models:* **"MJHP"; "MJHP-M"; "MJHP-F";**
Change description	**Change of the EU Auth. Representative** **"JaviTech e.K."** Sachsenhausener Str. 16, 65824 Schwalbach Am Taunus, Germany Technical Construction File ID: TCF-01 – No. of Rev. 4 – Date of Rev. 2022.12.12

MTIC Intercert, NB 0068, declares that pursuant to Article 120 (1) of Regulations (EU) 2017/745, since 26th May 2021, no certificate under the Medical Device Directive 93/42/EEC is allowed to be issued anymore. Consequently, pursuant to guidance MDCG 2020-3 this decision is valid together with and complements the above mentioned certificate.

MTIC Intercert, NB 0068, as Notified Body will continue to perform the surveillance activities according to Directive 93/42/EEC for the above-mentioned certificates which are still valid, as laid out in Regulation (EU) 2017/745, article 120 (3).

We, hereby that the above-mentioned EC-Certificate has been issued to the above-mentioned client and is still valid with the mentioned change description.

MTIC Intercert, NB 0068, hereby confirms that the afore mentioned change is not considered a significant change in the design and/or intended purpose as described in Regulation (EU) 2017/745, Article 120(3). The evaluation of documents related to the change has been completed and approved according to internal procedure PR-PC-DM-08-12.

Rif. Doc.: **DMP-11-23-91**

Data di emissione / *Date of issue*: **30/11/2023**

Dipl.- Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body

Sede Legale / Registered site: Via Leopardi, 14 – 20123 MILANO (MI) ITALY - Sede operativa / Headquarter: Via Moscova, 11 - 20017 RHO (MI) ITALY
Tel. +39.02.97071.800 - Fax +39.02.930.8176 - info@mtic-group.org – www.mtic-group.org