DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Kaz Europe Sàrl
Q-Center
Route de la Chaux 4
1030 Bussigny
Switzerland

Our ref.: CAB, Phone: 069 95427-8211, Fax: -388
E-Mail: carrie-ann.brown@dqs-med.de

Frankfurt a. M.
2023-03-23

Certification Confirmation Letter

To whom it may concern,

DQS Medizinprodukte GmbH is a Notified Body registered as NB 0297 according to § 15 Medical Devices Act – Directive 93/42/EEC and according to Regulation (EU) 2017/745 on medical devices. After 25th May 2021, Regulation (EU) 2017/745 superseded Directive 93/42/EEC.
We as a Notified Body will continue to perform the surveillance activities for certificates according to Directive 93/42/EEC issued by DQS Medizinprodukte GmbH, which are still valid.

Furthermore, DQS Medizinprodukte GmbH is an accredited certification body for management systems under the terms of DIN EN ISO/IEC 17021-1:2015 to carry out certifications of management systems according to DIN EN ISO 13485:2016.

DQS Medizinprodukte GmbH hereby confirms that the EC-Certificate (Certificate registration no. 381008 MR5 with the unique certification ID 170774273 valid from 2021-04-21 until 2024-05-26) has been issued to the following auditee:

Kaz Europe Sàrl
Place Chauderon 18
1003 Lausanne
Switzerland

in accordance with Annex II excluding section 4 of Council Directive 93/42/EEC concerning medical devices.

DQS Medizinprodukte GmbH hereby confirms that the new main Address of:

Kaz Europe Sàrl
Q-Center
Route de la Chaux 4
1030 Bussigny
Switzerland

is covered by the above mentioned Certificate. Kaz Europe Sàrl now has two sites, Bussigny and Lausanne which have been audited by DQS Medizinprodukte GmbH.

Yours faithfully,
DQS Medizinprodukte GmbH

i.A. Viviana Indraccolo
Regulatory Affairs Manager