BELGELENDİRME MERKEZİ BAŞKANLIĞI

Continuation of Surveillance Activities Declaration Form for Certificates Under the scope of MDD

Company Name: KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ.

Certificate No: 1783-MDD-238

Certificate Scope: ONEGEL LUBRICANT GEL WITH LIDOCAINE (STERILE)

Declaration Form Date: 21.05.2024

Declaration Form Number: 01/1783-MDD-238

Dear Sir/Madam,

The European Commission (EU) No 2023/607 amending the transitional provisions of the "Regulations (EU) 2017/745 and (EU) 2017/746 of certain medical devices and in vitro diagnostic medical devices, in order to reduce the risk of non-supply of medical devices; and The Council Regulation was published in the EU Official Journal on 20 March 2023, to enter into force as of 20 March 2023.

In this context, devices covered by Directive 93/42/EEC, provided that they fulfill the conditions specified in this Regulation:

(A) Class III devices and class IIb implantable devices, excluding sutures, staples, dental fillings, dental brackets, dental crowns, screws, wedges, plates, wires, pins, clips and connectors, until 31 December 2027.

(B) Class IIb devices, class IIa devices other than those covered above, and class I devices placed on the market in sterile condition or with measuring function, until 31 December 2028,

may be placed on the market or put into service.

A request has been made by the company to continue surveillance activities according to the provisions of "Regulation (EU) No 2023/607 of the European Parliament and of the Council amending the transitional provisions of Regulation (EU) No 2017/745 and (EU) No 2017/746 for certain medical devices and in vitro diagnostic medical devices" for the devices within the scope of the certificate numbered 1783-MDD-238, and, if any, related Amendment Confirmation Forms issued by our notified body under the scope of the 93/42/EC Medical Device Directive, given in Annex-1.

The declaration prepared by the manufacturer stating that the extension conditions specified in the Regulation (EU) No 2023/607 of the European Parliament and of the Council are met, and in case the company makes an application to a notified body designated within the scope of the 2017/745 EU Medical Device Regulation (MDR), the confirmation form stating that the conformity assessment application has been made to the notified body designated under the MDR is given in Annex-2.

The evaluation of the documents submitted by the manufacturer within the scope of the request regarding the continuation of surveillance activities is given in Annex-2. It is hereby declared that the surveillance activities of the company in question will be continued until the date of 26.09.2024 within

the scope of the 93/42/EC Medical Device Directive by our notified body for the devices given in Annex-3.

21 / 05 / 2024

Deputy Director of Directives

Ali Fuat ÇOLAK
Direktifler Müdürü V.

Annexes:

1- Copy(s) of Document and Amendment Confirmation Form, if any
2- Documents submitted by the manufacturer regarding the extension request and its evaluation
3- Devices for which surveillance activities will continue

In order to confirm the validity of this statement prepared regarding the validity of surveillance activities, the contact information is given below.

Tel: +90312 416 6461

e-mail: mdd@tse.org.tr

Annex-3 Devices for which surveillance activities will continue

Device Name	Device Class
ONEGEL LUBRICANT GEL WITH LIDOCAINE (STERILE)	Class III