

16.01.2024

To whom it may concern

The Sterile Lubricant Gel with Lidocaine (Lubragel), the Sterile Lubricant Gel with Lidocaine CHG Free (Urolube), Sterile Water Soluble Lubricating Gel (Hydrotouch) and the Sterile Injectable Implant for the Treatment of Vesicoureteral Reflux (Dexell VUR) are medical devices certified under 93/42/EEC.

We continue our planning for certification extension for The Sterile Lubricant Gel with Lidocaine (Lubragel), the Sterile Lubricant Gel with Lidocaine CHG Free (Urolube), Sterile Water Soluble Lubricating Gel (Hydrotouch). The document extension process will be completed by 05/2024.

For the Dexell VUR; According to the response (Annex-1) we received from the Ministry of Health following our application for document extension, the product's certification period has been extended until 12/2027. The Medical Devices Regulation (EU) 2017/745 certification process of the product is ongoing.

Bengi Melahat ERDEM
Kalite Güvence Sorumlusu
Quality Assurance Responsible
16.01.2024