

SFDA

المملكة الصربية السعودية الهيئة العامة للفذاء والدواء

> (٥٥٥) قطاع الأجهزة و المنتجات الطبية

(255) Medical Devices Sector

ANNOUNCEMENT . * / 1 1 / MDS-AN . 1 A

<u>SUBJECT</u>: Publication of Authorized Representative application fees and review times.

<u>ADDRESSEES</u>: Authorized Representatives for both local and overseas manufacturers.

Authorized Representative application fees and review times will be as follow:

Medical Device Authorized Representative license (AR) Processing Fees Lead time The Basis of the application for SFDA Authorized Representative Annually (Working Days) Per manufacturer mandate 5200 SR 20 days Per manufacturer mandate * Year 5200 SR * No. of Years 20 days Notes: The issued SFDA AR license will be valid for One (1) Year unless the applicant choose more than one year. By choosing validity for more than a year, the fees shall be calculated for the number of years chosen based on mandate validity For Renewing the SFDA AR license, the same fee will be charged.