

إذن تسويق جهاز / منتج طبي

Medical Device Marketing Authorisation

Issuing Date (dd/mm/yyyy) : 31/05/2019 Authorization Number : MDMA19050496 : رقم الاذن : 1440/09/26 تاريخ الإصدار
Expiry Date (dd/mm/yyyy) : 23/04/2022 Issuing Number : 1 : رقم الإصدار : 1443/09/22 تاريخ الانتهاء

This authorisation is issued in accordance with the Medical devices interim regulation (MDIR) and in particular to the implementing rule MDS-IR6 for Medical Device Marketing Authorisation (MDMA)

أصدر هذا الإذن بموجب لائحة رقابة الأجهزة والمنتجات الطبية والقواعد الإجرائية (MDS-IR6) الخاصة بإذن تسويق الأجهزة والمنتجات الطبية.

This authorization allows:

Manufacturer Identification Number M06543
Diasoft B.V.
Klepelhoek 11 , Leusden 3833 GZ Netherlands

هذا الإذن يخول :

To market the medical device listed below in the Kingdom of Saudi Arabia.

بتسويق الجهاز / المنتج الطبي المحدد أدناه في المملكة العربية السعودية.

Medical Device Description	Dialysis Electronic Patient Record Software and Device Connectivity Hardware	وصف الجهاز / المنتج الطبي
Mdeical Device National Listing Number	MM06543SFDAA0001	رقم قيد الجهاز / المنتج الطبي في السجل الوطني
Brand / Trade Name	Diamant 2	الاسم التجاري

المدير التنفيذي للتسجيل و التراخيص

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Viewing Product:

Product Details

Name	Dialysis Electronic Patient Record Software and Device Connectivity Hardware
Category Name	Medical Software
Jurisdiction	Europe
Device Type	Medical Device
Device Classification	ClassIIb
Product Number	MM06543SFDAA0001
Intended purpose of the medical device type	1. Registration of administrative demographic patient data 2. Registration of nurse observations 3. Prescription of nurse actions 4. Planning of nurse
Trade / Brand Name	Diamant 2
Model Number	- Unviersele SmartConnector 20.30.100 - Mini SmartConnector 20.30.110 - SmartConnector Power 20.40.130
Manufacturer's Device Identifier Number	- Unviersele SmartConnector 20.30.100 - Mini SmartConnector 20.30.110 - SmartConnector Power 20.40.130
Format of medical device identifier number(s) that will appear on labelling for traceability purposes	Serial Number and Version Number
GMDN	N/A
UMDNS	N/A
Other Code	N/A

The following Authorization exist for this product:

Certificate Number	Issue Date	Expiry Date	Hijri Issue Date	Hijri Expiry Date
MDMA19050496	31/05/2019	23/04/2022	1440/09/26	1443/09/22

Manufacturer Details

Name	Diasoft B.V.
Address	Klepelhoek 11
Phone Number	+31(0)33 494 4460

Current Authorized Representative Details

Name	Baxter AG
Address	Baxter AG. Scientific Office Daren building. Al'Ahsa Street, Rabwah Sq. Riyadh

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