

بمقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman
2040
Vision

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No...31..... dated 17/02/22 Regarding NCMR FSN of HeartWare Ventricular Assist Device (HVAD) from (mrf: Medtronic SA).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



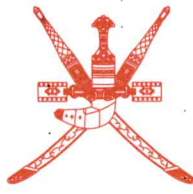
PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧٨٨٩ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489

dgpa_dc Email: dg-padc@moh.gov.om



Circular No. 31 / 2022

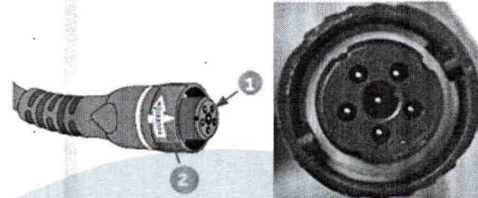
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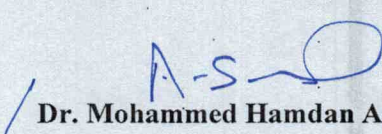
17-02-2022

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FSN of HeartWare Ventricular Assist Device (HVAD) of from Medtronic SA

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16012
Product	HeartWare Ventricular Assist Device (HVAD).
Description	Heartware Ventricular Assist System - Implantable ventricular circulatory assist system.
Manufacturer	Medtronic SA
Affected	Product Name: Controller AC Adapter; Product Number: 1425, 1430 Product Name: Controller DC Adapter; Product Number: 1440 Product Name: Battery; Product Number: 1650DE
Local Agent	Al Zahrawi Medical Supplies LLC.
Reason	It was identified that additional clarity was required around cleaning the Power Source Connectors (Controller AC Adapter, DC Adapter, and Battery).
Action	1. Medtronic is advising customers that the cleaning instructions for the Controller AC Adapter, DC Adapter and Battery section in the IFU and PM will be updated. 2. Contact the local agent for remedial action.
Product Picture	 <p>1 Pins (6) 2 Power Source Connector</p>
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om


Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

