Date: Dec 13th, 2023
Reference Number: SG-2312-413-H

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector
National Center for Medical Devices Reporting

رسالة سلامة

Safety Communication

To: Healthcare Provider	**إلى: مقدمي الرعاية الصحية**

Title	Using Myval Trans-catheter Heart Valve in un-authorized intended use (Pulmonary position)	**العنوان**
Medical Device Description	Myval Trans-catheter Heart Valve	**اسم ووصف الجهاز/المستلزم الطبي**
Medical Device Products Identifier	All	**الأرقام للجهاز/المستلزم الطبي**
Manufacturer	Meril Life Sciences Pvt. Ltd.	**اسم المصنع**
Authorized Representative	Eyad I Alshedwy Comm Est	**الممثل المعتمد**

Medical Devices Marketing Authorization (MDMA)	MDMA-1-2019-4091	**إذن التسويق**
Potential /Associated risks	SFDA can not ensure the safety and effectiveness of using Myval valve in un-authorized intended use (pulmonary heart position). This device has been approved by SFDA for relief of aortic stenosis indication.	**المخاطرالمحتملة/ المرتبطة بالجهاز أو المستلزم الطبي**
Recommendations	• Please make sure the relevant personnel in your facility is aware of this contraindication "Not for pulmonary heart valve replacement" and use the device according to the indicate approved intended use (IFU) as below: "Transcatheter Heart Valve (THV) and accessories are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis as judged by a heart team (including a cardiac surgeon) and in patients who are at a risk for open heart surgical therapy (Society of Thoracic Surgeons operative risk score of ≥4% risk of mortality at 30 days)."	**التوصيات**
For Reporting	SFDA 19999 مركز الاتصال الموحد · NCMDR · تيقظ Saudi Vigilance	**للإبلاغ**