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Medical Devices Sector

National Center for Medical Devices Reporting

الهيئة الحامة للضفاء والحواء Saudi Food & Drug Authority

Safety Communication

رسالة سلامة

الى: مقدمي الرعاية الصحية إلى: مقدمي الرعاية الصحية

Title	Remind of the importance to ensure the correct assembly position of the carabineer in the Birdie lifter arm, and as well the correct attachment of the hanger bar into the carabineer.	المعنوان:
Medical Device Description	Invacare Birdie lifter	اسم ووصف المستلزم الطبي
Manufacturer	Invacare Portugal, Lda Sociedade Industrial e Comercial de Ortopedia	اسم المصنع
Distributor	Regulatory Standards Consultation Office	الموزع

Medical Devices Marketing Authorization (MDMA)	MDMA-2-2024-0388	إذن التسويق
Potential /Associated risks	The potential of a serious adverse event related to Invacare Birdie lifter and carabineer attachment due to the incorrect assembly position of the carabineer in the Birdie lifter arm, and as well the incorrect attachment of the hanger bar into the carabineer.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	Ensure the correct assembly position of the carabineer in the Birdie lifter arm, and as well the correct attachment of the hanger bar into the carabineer by following the improved Maintenance checklist included in the updated instructions for use of the device, under "The hanger bar" section, with the additional point to check this specific topic during regular maintenance.	التوصيات

For Reporting





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