EU Declaration of Conformity

DOC-01
Rev. 01

Revision History

CO#	Rev	Description of Change	Issue Date
NA	NA	New Release	21/12/2022
01	01	Added Zoof as manufacturer	03/04/2022

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We the Manufacturer:	Zoof Wheelchairs BV, Voltaweg 22,City Echt, postal code 6101 XK, Country- Netherlands	
SRN Number	NL-MF-000033100	
Product Name & Product Code	Product Name	Basic UDI-DI Code
	Zoof Urban	05419980316929
	Zoof Classic	05419980316936
Intended purpose	A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.	
In accordance with the following Directive and Classification:	We herewith declare that the above mentioned products meet the provisions of the following Regulation EU MDR 2017 for medical devices. All supporting documents are retained under the premises of the manufacturer. The Company has been subjected to the procedures laid down in Annex II and III. Declaration of conformity defined as per Annex IV of Regulation EU MDR 2017 and CE marking used as per Annex V for EU MDR 2017.The scope device is classified as Class 1 device as per Rule 1 of Annex VIII of EU MDR 2017.	
Product Family:	Manual Wheel Chairs	
Device Classification	**Product Name**	**Classification**
	Manual Wheel Chair	Class I - Rule 1 - Non-Invasive device, no other rule applies
Rule	Regulation (EU) 2017/745, Chapter V, Section 1, Article 51 & Annex VIII	
GMDN	**Product Name**	**GMDN Product Classification**
	Manual Wheel Chair	**Wheelchair, attendant/occupant-driven, bimanual-chain-operated, collapsible-** A wheeled personal mobility device that incorporates a seat-support system for a person with a disability or a person without the full capacity to walk (not bariatric) designed to be manually propelled by the user while seated in the device or by an attendant. The occupant moves the device by rotating one or two handles on a toothed wheel(s) with a chain link(s) to rotate the drive wheel(s). An attendant moves the device by pushing or pulling handles on the device. The device may be disassembled or folded for transport.

The product is in conformity with the applicable requirements of the following documents:	Standard	Standard Title	EN Equivalent Standard
	EN-12183:2014	Manual wheelchairs - Requirements and test methods	EN-12183:2014
	ISO 14971	Medical Devices-Application of risk management to medical devices, with Amendment 1: Rationale for requirements	EN ISO 14971:2012
	ISO 10993-1	Biological Evaluation of Medical Devices	EN ISO 10993-1:2009
	ISO 13485:2016	Quality management systems — Requirements for regulatory purposes	EN ISO 13485:2016

Notified Body:	Self-Declaration
Date CE Mark Affixed:	**03/04/2023**

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The product complies with all General safety and performance requirements. Manufacturer has sole responsibility for issuing the EU declaration of conformity.

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Name	**Tim Kortekaas**	
Place:	Voltaweg 22,City Echt, postal code 6101 XK, Country- Netherlands	
Signature		
Position	Quality & Finance Manager	
Date / Applied Serial Number	**Date: <03/04/2023>**	**Serial Number: <01>**