EC Declaration of Conformity

CE

Manufacturers Name:	XentiQ Partners Pte Ltd
Manufacturers Address:	35 Joo Koon Circle, 6th Floor Vicplas Bldg, Singapore 629110
SRN (Single Registration Number):	SG-MF-000009360
Authorized Representative Name (if applicable):	Medical Technology Promedt Consulting GmbH, SRN DE-AR-000000085
Authorized Representative Address (if applicable):	Altenhofstrasse 80, 66386 St. Ingbert, Germany
CND code:	Y120609 Walking frames with chair, 4 wheels

Devices:

Name	Basic UDI-DI:	Product code/SKU:
Voyar FROG M1-X	8813004300009W4	DP1601-1014M
Voyar FROG M2-X	8881300430016	DP1601-1012M
Voyar FROG M3-X	8881300430023	DP1601-1013M
Voyar FROG M4-X	8881300430030	DP1601-1011M
Voyar FROG L1-X	8881300430047	DP1601-1014L
Voyar FROG L2-X	8881300430054	DP1601-1013L
Voyar FROG L3-X	8881300430061	DP1601-1012L
Voyar FROG L4-X	8881300430078	DP1601-1011L

Intended Purpose	The FROG gait trainer provides gait and balance support in patients with walking difficulties and can be used in the rehabilitation of gait. It has weight bearing handles and arm rests and a foldable seat as resting position. It can be used indoors in hospitals, therapy centers and ambulatory activities at home.
Classification:	I
Notified Body name:	NA
Notified Body Address:	NA
Conformity assessment route:	XentiQ Partners Pte Ltd uses the following procedures for the CE-labelling of their products according the Regulation MDR 2017/745: Rule (according to Annex VIII, MDR): Rule 1; Conformity assessment procedure: Article 52 (7) MDR

This declaration of conformity is issued under the sole responsibility of XentiQ Partners Pte Ltd. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by TÜV Rheinland.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

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Ulrich SCHRAUDOLPH
Executive Director
Singapore, 15.11.2021