Certificate of Registration

Certificate No. **CE/CAN/2010/07/02**

Issued To: **Raz Design Inc**
135 Railside Road,
Toronto, ON,
Canada
M3A 1B7

Legal Manufacturer [SRN: CA-MF-000004895]

Issued By: **Advena Limited**
Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta.

EC-REP [SRN: MT-AR-000000234]

EU Competent Authority: **Malta Medicines Authority (MMA)**
Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000
Malta.
Tel: +356 2343 9000
Email: info.medicinesauthority@gov.mt

We hereby declare that:

- Device registrations for the medical devices mentioned within this certificate have duly been completed with the Malta Medicines Authority (MMA) the Competent Authority of Malta.
- Due to the 26th May 2021 Date of Application of Regulation (EU) 2017/745 (MDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 93/42/EEC (MDD) through Article 120 (3) of Regulation (EU) 2017/745 is legitimately permitted.
- Due to the 26th May 2022 Date of Application of Regulation (EU) 2017/746 (IVDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 98/79/EC (IVDD) through Article 110(3) of Regulation (EU) 2017/746 is legitimately permitted.

Anthony Kirby – Managing Director

Date of Issue: 22 June 2022 **AR Cover Begins:** 01 July 2022 **AR Cover Ends:** 30 June 2023

This certificate is subject to the organisation maintaining their documentation in compliance with the EU legislation as indicated in this certificate.

This certificate is for the exclusive use of Advena Ltd's clients and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

Appendix A

Product Details, Names or Trade Names	EU Legislation	Classification	Device Registration Reference(s)
Raz Mobile Shower Commode Chairs	MDR	Class I	MT-MDF03-AA462A

Declaration of Conformity for Raz Mobile Shower Commode Chairs

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name	**Raz Mobile Shower Commode Chairs**
Legal Manufacturer: (Name on Label)	**Raz Design Inc.** 22 Howden Road, Toronto, ON, M1R 3E4 Canada
Variants:	As per Appendix II of this document under Product Listing / Schedule
Intended Use:	Individually configured indoor mobile commode chairs for use during showering and toileting.
MDR Classification:	Class I
Notified Body:	Not Applicable for Class I
Basic UDI-DI	628758RAZDESIGNINC2004V9
EU Authorized Representative:	**Advena Limited** Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta
Medical Device Regulation Assessment Route:	Self-certification as Class 1 by Raz Design Inc. according to Annex VIII of Regulation (EU) 2017/745

Name: Nelson Pang

Position: President

Signature: 

Date: 2021-04-29

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Declaration of Conformity Version History

Version	Compiled by	Position	Date	Description
1.0	Mehrnaz Tabibi	QAM /QMR	2017-05-18	First Issue
2.0	Shaunelle Valley	QAM /QMR	2019-02-06	Second issue
3.0	Shaunelle Valley	QAM /QMR	2020-03-03	Third issue – transition to MDR 2017/745
4.0	Shaunelle Valley	QAM /QMR / PRRC	2021-04-27	Fourth Issue

*QAM – Quality Assurance Manager *QMR - Quality Management Representative *PRRC - Person Responsible for Regulatory Compliance

Appendix II – Applicable Standards

The present declaration is also in conformity (partial/full) with the following European standards and common specifications:

Standard / Document Name	Description
EU 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to MedicalDevices
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
ISO 9999: 2016	Assistive products for persons with disability – Classification and terminology
ISO 10993-1: 2018	Biological Evaluation of Medical Devices
ISO 7176	Wheelchairs: Requirements and test methods for static, impact and fatigue strengths
AS/NZS 3973: 2009	Requirements for chairs intended for use in showers and toilets
BS EN 1021-1: 2014	Furniture. Assessment of the ignitability of upholstered furniture. Ignition source smoldering cigarette.
BS EN 1021-2: 2014	Furniture, Upholstered furniture, Fire tests, Ignitability, Test equipment, Reports, Testing conditions

* Details of applicability found in RTD001r00

Appendix III – Product Listing / Schedule

A) Product variations offered by Raz:

Product Code	Description/Name	GMDN Code
Z100	Raz-AP: Raz Attendant Propel Chair	40539
Z160	Raz-AP600: Raz Attendant Propel Bariatric Chair	40539
Z200	Raz-SP: Raz Self Propel Chair	40539
Z260	Raz-SP600: Raz Self Propel Bariatric Chair	40539
Z303	Raz-CAT: Compact Attendant Tilt Chair	40539
Z300	Raz-AT: Raz Attendant Tilt Chair	40539
Z360	Raz-AT600: Raz Attendant Propel Bariatric Chair	40539
J102	Jaz-AP: Attendant Propel Economy Chair	40539
J202	Jaz-SP: Self Propel Economy Chair	40539
Z333	Raz-ART: Raz Attendant Rotational Tilt Chair	40539
Z122	Züm-AP: Züm Attendant Propel Chair	40539
Z222	Züm-SP: Züm Self Propel	40539

B) Available accessories can be found on the Accessories List RTD011r00 Rev. Date: 2021-04-23

***Please note listed items, where applicable, are available in varying sides and / or sizes or are configured to the user's requirements**