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DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

| Type of Equipment | Product Name(s) | Model/Number(s) |
|----------------------------|--------------------------|--|
| Powered Exercise Equipment | Gait Trainer 3 Treadmill | 950-400, 950-401, 950-402 950-403, 950-404, 950-405 950-406, 950-407, 950-408 950-413 |

Serial Number [ENTER]

MANUFACTURER

| Name of Company | Address | Representative |
|------------------------------|---|---|
| Biodex Medical Systems, Inc. | 20 Ramsey Road Shirley, NY 11967-4704 USA | Clyde Schlein <i>Vice President, Regulatory Affairs & Compliance</i> |

AUTHORIZED REPRESENTATIVE

| Name of Company | Address | Telephone/Email |
|-----------------|--|--|
| Ergo Europe | Prinsessegracht 20 2514 AP The Hague The Netherlands | Phone: +31.70.345.8570 Fax: +31.70.346.8570 |

REGISTRATION INFORMATION

| Notified Body and ID# | CE Certificate No & Expiration Date | Date CE Marking First Applied |
|-----------------------|-------------------------------------|-------------------------------|
| Intertek Services | 41312068-01 July 20, 2023 | N/A |

CONFORMITY ASSESSMENT

| Device Classification | Route to Compliance | Standards Application |
|------------------------------|---|---|
| Class I Measuring Rule 12 | Annex V of MDD 93/42/EEC Council Directive | IEC/EN 60601-1, Ed 3 IEC 60601-1-2:2007 UL 60601-1:2003, Ed 1 rev 2006 CAN/CSA C22.2 No.:601-1-M90 |

QUALITY SYSTEM REGISTRAR

Intertek Services Certified Quality Management System:
ISO 13485:2016 Certificate: 0084059

Biodex Medical Systems, Inc. declares the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices.

Company Representative: Clyde Schlein

Title: Vice President, Regulatory Affairs & Compliance

Date: May 1, 2019

No. 137 Rev. I

Biodex Medical Systems, Inc.

20 Ramsey Road, Shirley, New York, 11967-4704, Tel: 800-224-6339 (Int'l 631-924-9000), Fax: 631-924-9241, Email: info@biodex.com, www.biodex.com

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Signature:

A handwritten signature in black ink, appearing to be 'G. B. B.', with a long horizontal flourish extending to the right.

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