**DECLARATION OF CONFORMITY**

<table>
<thead>
<tr>
<th>APPLICATION OF COUNCIL DIRECTIVE(s) AND NATIONAL REGULATION OF SWEDEN</th>
<th>93/42/EEC as amended by 2007/47/EC : LVFS 2003:11</th>
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<tbody>
<tr>
<td>DATE OF ISSUE</td>
<td>September 25, 2018</td>
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<tr>
<td>TYPE OF EQUIPMENT</td>
<td>Thyroid Uptake Probe</td>
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<tr>
<td>BRANDNAME</td>
<td>Atomlab 960 Thyroid Uptake System</td>
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<tr>
<td>MODEL NUMBER(s)</td>
<td>187-600, 187-601, 187-602</td>
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<td>SERIAL NUMBER</td>
<td>SAMPLE</td>
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| STANDARD(s) TO WHICH CONFORMITY IS DECLARED | IEC 60601-1-6 3rd Ed.  
IEC 60601-1-6 2nd Ed.  
CAN/CSA C22.2 No.601-1M90 2nd Ed.  
IEC 60601-1-6  
ANSI 60601-1 3rd Ed.  
IEC 60601-1 3rd Ed.  
IEC 60601-1 2nd Ed.  
UL 60601-1 (2003)  
IEC 62366:2007  
EMC Retlif R-14213 (includes the following):  
Conforms to the emissions requirements of EN60601-1-2:2007/AC:2010  
CISPR 11 Edition 5.1:2010-05 Conducted Emissions, Group 1, Class A  
CISPR 11 Edition 5.1:2010-05 Radiated Emissions, Group 1, Class A  
IEC 61000-3-2 Edition 3.2: 2009 Harmonics  
IEC 61000-3-3 Edition 2.0: 2008-06 Flicker  
Conforms to the immunity requirements of EN60601-1-2:2007/AC:2010:  
IEC 61000-4-2 Edition 2.0: 2008-12 Electrostatic Discharge  
IEC 61000-4-3 Edition 3.2: 2010-04 Radiated Immunity  
IEC 61000-4-4 Edition 2.1: 2011-03 EFT/Burst, Power Leads  
IEC 61000-4-5 Edition 2.0: 2005-11 Surge Immunity, Power Leads  
IEC 61000-4-8 Edition 2.0:2009-09 Power Frequency Magnetic Fields  
IEC 61000-4-11 Edition 2.0:2004-03(Int. sheet 1) Voltage Dips and Interrupts |
| BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM | ISO 13485:2003 Certificate #98-1091h-03 |
| CLASS | IIa Annex II |
| NOTIFIED BODY | Intertek Semko AB  
Torshamngatan 43  
Box 1103  
SE-164 22 Kista, Sweden |
| E.C. CERTIFICATE # and Expiration Date | 41313009-01 July 20, 2023 |
| CE IDENTIFICATION # | 0413 |

**ISSUED BY MANUFACTURER:**

Biodex Medical Systems, Inc., 20 Ramsey Road, Shirley, New York 11967-4704 USA

I, the undersigned, hereby declare that the equipment specified above conforms to the Directive(s) and Standard(s) as specified.

**Authorized European Representative**

Clyde Schlein  
Vice President, Regulatory Affairs & Compliance

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