

28 June 2023

Re: Regulation (EU) 2023/607 amending Regulations (EU) 2017/745

Dear European Union Distributors,

Biodex is in the process for MDR certification with our Notified Body Intertek Semko with an expected completion by December 2023. Although our current MDD certificates are set to expire on July 20, 2023, Biodex qualifies for the MDD certificate extension provision since our devices:

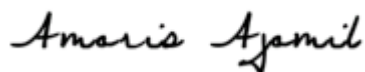
- Were certified by a notified body under the Medical Device Directive 93/42/EC (MDD), and
- The MDD certificates were valid at the date of application of the MDR (26 May 2021), and
- Before the certificate expired the manufacturer and a notified body have signed a written agreement with a notified body for the conformity assessment of the device

The extension provision allows Biodex to continue to market in the EU with the MDD certificates past July 20, 2023 until they are replaced by the MDR certificate. Biodex is able to operate under the extension provision until December 31, 2028.

Also attached is the executed agreement between Biodex and our Notified Body for the MDR certification.

Affected Certificates	Devices
EC-41312068-02	Gait trainer 3 950-400, 950-401, 950-402, 950-403, 950-404, 950-405, 950-406, 950-407, 950-408
	Balance SD 950-440, 950-441, 950-444
	BioSway 950-460, 950-461
	Offset Unweighing System 945-480
EC-41313009-03	System 4

Best regards,



Amaris Ajamil, PhD, RAC
Vice President, Quality and Regulatory Affairs
Salona Global Medical Device

INTERTEK BUSINESS ASSURANCE

MEDICAL DEVICE MANAGEMENT SYSTEM CERTIFICATION

Prepared by:

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Issue Date: October 13, 2022

[intertek.com](https://www.intertek.com)



October 13, 2022

Mary Anne Yusko
49 Natcon Drive
Shirley, New York 11967
United States

Phone: +1 201-825-9500 ext 342
Email: MYusko@mirion.com

Quote #: mr20221013

Dear Mary Anne,

Proposal for Biodex Medical Systems, Inc.

On behalf of Intertek, please accept my sincere thanks for allowing us the opportunity to present this proposal to serve as your certification body.

Once you decide to move forward, we will develop an audit program that is based on your specific needs and objectives. We will establish regular communications with your organization and maintain a long-lasting relationship based on trust and quality of service.

Sincerely,

Marina Rupp

Marina Rupp
Business Development Manager
Business Assurance

Direct +1-616-656-0634
Email marina.rupp@intertek.com
Intertek, 4700 Broadmoor Ave. SE Suite 200, Kentwood MI 49512

About Intertek

Intertek is a leading Total Quality Assurance provider to industries worldwide. Through our network of more than 1,000 laboratories and offices and over 42,000 people in more than 100 countries, the Group is re-defining the industry with our Total Quality Assurance proposition. We go beyond physical quality control to provide total peace of mind through our innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains:

- **Auditing:** We verify your business performance against proprietary, international, or local regulatory criteria, ensuring your products, processes, and systems adhere to applicable quality, health, environmental, safety, and social accountability standards.
- **Testing:** Our global testing expertise includes safety, quality control, prototype testing and product benchmark testing.
- **Inspection:** We provide a range of inspection services including factory and quality, custody transfer, pre-production, in-production, final random sampling, pre-shipment, and loading supervision.
- **Certification:** Through an extensive range of global accreditations, recognitions, and agreements, we provide certification services for manufacturers, retailers, and traders selling products in virtually every market in the world.
- **Training:** Intertek's experts have the experience to assure your key staff, management, and suppliers will be up to date on key compliance issues, technical expertise, and more.
- **Quality Assurance:** We test, audit, and inspect various systems, processes, raw materials, semi-processed products, and fully finished products.
- **Technology:** Our innovative web-based platforms, anchored in Intertek's extensive expertise, allow for evaluating and monitoring, offering an efficient mechanism for continuous improvement.
- **Global Reach:** Our 3000+ auditors available in 130+ countries offer reliable assurance across a wide range of industries, wherever you do business.

Accreditation

Intertek is accredited by several internationally recognized accreditation bodies to provide management systems registration services. Full details are available on our website at

<http://www.intertek.com/auditing/accreditation-for-management-systems-certification/>.

Resources

Intertek has a global pool of auditors and assessors that is constantly growing and developing. Our auditors each bring many years of field experience, education, and training with them. Our qualification process, which satisfies the requirements of ISO 17021-1 and program-specific requirements, provides assurance that auditors from all Intertek offices are qualified at the highest level to perform their assessment activities.

This proposal is based on the information provided by the client and **valid for 10 days**. Variation in the management system or scope may require a revised proposal to properly meet your service request. Renewed or update proposal might initiate further costs. Quote #: mr20221013

Scope of Certification

Audit Criteria: Certification Body and Accreditation	<p>EU MDR 2017/745 Annex IX: Intertek Medical Notified Body AB (MPA - Läkemedelsverket)</p> <p>MDD 93/42/EEC Annex II and Annex V: Intertek Semko AB (SWEDAC)</p> <p>ISO 13485:2016 under MDSAP: Intertek Testing Services NA Inc. (IMDRF)</p> <p>Including the following regulatory requirements:</p> <ul style="list-style-type: none"> • Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) • Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001 • Canada: Medical Devices Regulations – Part 1- SOR 98/282 • Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable) • United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)
Scope of certification**:	<p>MDD Annex II: Physical therapy and rehabilitation equipment; Class II a</p> <p>MDD Annex V: Measuring: Radionuclide calibrators, Class I, measuring</p> <p>Measuring: Physical therapy and rehabilitation equipment Class I, measuring</p> <p>MDR: Class I(m), Class I devices with a measuring function, Class IIa, Rehabilitation devices</p> <p>ISO 13485/MDSAP: The design, manufacture, installation, service and support of physical medicine products, rehabilitation products, and radiology products and accessories. The service and support of nuclear medicine products and accessories.</p>
Locations:	49 Natcon Drive Shirley, New York 11967 – 85 Employees (FTE*)
MD codes/NACE Rev.2:	MDA 0313, MDS 1009, MDS 1010, MDT 2001, MDT 2002, MDT 2010, MDT 2011, MD 0103, MD 1108, MD 1109, MD 1201, MD 1401
Audit frequency:	Annual
Current Audit Day Rate: (audit day rates are subject to annual updates)	\$ 3,200

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Notes:

*FTE (Full Time Employee equivalent). The audit man-day calculations are based on the FTE number. If the FTE changes, during a certification cycle, Intertek has the right to increase or decrease the audit duration without signing a new contract with the client. In the case of changed audit time duration, due to FTE change, an amendment to this contract will be set up. The amendment is valid without signatures. FTE changes must be reported to Intertek. Omitting to report changed FTE constitutes a violation to the certification agreement. Changes of FTE shall be reported at least 30 calendar days before the scheduled audit.

**Scope is preliminary in this proposal and will be finalized after the initial assessment.

Audit-Day Table

The number of audit-days required to be spent on-site for certification, surveillance, and re-certification audits is mandated by the International Accreditation Forum (IAF) and/or other program-specific requirements.

The table below is an estimate of the number of audit-days for the sites covered by your certification. Please note that this calculation is based on the information you provided in our Client Information Form, considering the following adjustment factors:

- Factors increasing audit time: not applicable.
- Factors decreasing audit time: not applicable.

If you find that any of the information is incorrect, please notify us immediately so we can update these audit-day calculations.

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Audit Estimate

AUDIT ELEMENT	YEAR 2023	YEAR 2024	YEAR 2025	YEAR 2026	YEAR 2027	TOTAL
Surveillance 2	3.5 \$9,100					\$9,100
Stage 1 (MDR)	2.5 \$8,000					\$8,000
Stage 2 (MDR)	6.0 \$19,200					\$19,200
Surveillance 1 (MDR) Re-certification (MDSAP)		7.5 \$24,000				\$24,000
Surveillance 2 (MDR) Surveillance 1 (MDSAP)			4.0 \$12,800			\$12,800
Surveillance 3 (MDR) Surveillance 2 (MDSAP)				4.0 \$12,800		\$12,800
Surveillance 4 (MDR) Re-certification (MDSAP)					7.5 \$24,000	\$24,000
Annual Fee (MDD)	\$5,270					\$5,270
Annual Fee (MDR)	\$9,700	\$6,930	\$6,930	\$6,930	\$6,930	\$37,420
Annual Fee (MDSAP)	\$1,500	\$1,500	\$1,500	\$1,500	\$1,500	\$7,500
Total	\$52,770	\$32,430	\$21,230	\$21,230	\$32,430	\$160,090

Notes:

All fees exclude travel expenses and additional activities

Estimate is subject to updated prices and not guaranteed.

Annual fee is non-refundable, subject to change and not guaranteed. Depending on the programs/audit criteria, annual fees may be billed at different time during the year, not necessarily billed in conjunction with the audit.

For EU MDR, the annual fee will initially be invoiced at the issuance of the certificate and will be prorated, i.e. the cost of the first annual fee will be invoiced as pro rata from signing formal application. The annual fee for MDR will be invoiced in January every year thereafter for the coming year.

For MDSAP, and EU MDR, audit reports must be in English.

ISO 13485 re-certification estimate is based on current information and is subject to change.

During Stage 1, the auditor may identify critical suppliers that must be audited during Stage 2, this will add time to the duration indicated in the table above.

For EU MDR, the duration of Stage 2 may increase depending on input from the Technical Document Assessments and Stage I audit.

For EU MDR, the Stage 2 audit may only be performed after the initial TD assessment is completed.

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The subsequent certification cycle will be covered by a new contract/agreement.

For quotations issued to transfer certificates from another accredited Certification body (accredited by an accreditation body who is signatory of an MLA), the above proposed services are conditional to the successful completion of the transfer review (technical review of mandatory information).

This contract does not include all pricing for Notified Body/Approved Body services. The current pricing is attached and is subject to change. This attached pricelist details the current annual and periodic certificate fees, fees related to the review of technical documentation and additional administrative fees.

Conformity Assessment Process

After the initial certification audit, surveillance audits will be scheduled at an annual frequency. The surveillance visits will be planned in such a manner that all key business processes will be reviewed within a three-year audit cycle. Three years after the initial certification audit, a re-certification audit will be conducted to perform a full on-site assessment.

Additional information specific to MDSAP:

Intertek may perform unannounced audits in addition to regular annual audits under the MDSAP program: 1) upon request by the recognizing Regulatory Authority(s); 2) if previous audits indicate serious and/or frequent nonconformities; 3) if specific information provides reasons to suspect serious non-conformities of the devices, or of their manufacturer.

Additional information specific to MDD:

- In addition to the activities listed above, mandatory MDD unannounced audits will be performed at least once every three years.
- Additional assessment activities for MDD (after MDR date of application): PSURs and PMS plans are to be reviewed on a regular basis according to requirements in MDR. The sampling plan throughout the EC certificate validity period will be determined by the Notified Body. These costs are over and above this proposal.

Additional information specific to MDR:

- In addition to above, the MDR audit cycle normally follows a five-year cycle. This means that every fifth year a re-certification audit will be performed for MDR, independent of the cycle for other certification programs.
- Conformity assessment activities will be carried out by a subsidiary of the Notified Body.
- In addition to the activities listed above, mandatory MDR unannounced audits will be performed at least once every five years.
- According to MDR, the Notified Body is requested to perform product tests of products that are placed on the European market, when needed. The costs for these tests are not included in this estimate. If a product test is requested to be performed by the Notified Body, the Notified Body will inform the manufacturer and propose the cost for the test(s). The manufacturer must approve the cost before the test is done (approval not applicable to test performed during unannounced audits). If the cost for testing is not approved, the Notified Body has the right to suspend or withdraw the affected EC-certificate and may also terminate the agreements.

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- According to MDR, the Notified Body is requested to perform audits at critical supplier to the legal manufacturer. Such critical supplier audits have typically a duration of one day and are not included in the calculations in this proposal. Any audit of a critical supplier (if not an unannounced audit) is communicated to the client in advance. The cost for the audit at a critical supplier is the responsibility of the legal manufacturer (the client signing this agreement). Not allowing the Notified Body to add time to audit critical suppliers is a violation of the certification agreement and can lead to suspension or withdrawal of certification.
- MDR Technical Documentation (TD) review:
 - For initial certification, the TD review shall be completed before the Stage 2 audit is performed. The Stage 1 audit may be performed concurrently with the TD review.
 - For initial certification and re-certification under MDR, technical documentation (in conformance with MDR Annex II and III) shall be sampled in accordance with MDR Article 52. The information in the CIF (Client Information Form) is the basis for the Technical Documentation to be sampled. Below is an estimated cost for assessment of Technical Documentation prior to initial certification. Further sampling, as required by MDR, will be invoiced according to pricelist.

Class of device	Number of TD	Estimated cost*
Ila	1	\$ 21,390 USD
Ilb		
Ilb implantable		
III		
Special		

* The above costs only include a first review of the documentation, if non-conformities are identified, management of these will add to the cost. For most clients this means that for each sampled technical documentation, two or three additional review rounds are usually needed. As such, the above costs can be increase. See current price list for further information.

The estimated cost for TD assessments is based on the basic TD cost and is subject to change and will be according to valid pricelist.

- Technical documentation is reviewed on an annual basis. In accordance with MDR, at least one technical documentation file should be sampled each year and shall cover the full range of devices over one certification cycle. The sampling plan throughout the EC certificate validity period will be determined by the Notified Body. If sampling of the full range of devices is completed before the end of the certification cycle, the surveillance audits will focus on specific PMS activities, with potential addition of audit time. These costs are over and above this proposal (below table is only for initial certification sampling) and will be invoiced as per current price list. The costs for maintaining a certificate are charged annually and a fee for MDR re-certification is charged at least every five years. These costs and current pricelist will be updated on a regular basis based on the general cost development for Notified Bodies.

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Unannounced audits

- The unannounced audit will be performed by an audit team of at least two (2) auditors for at least one (1) day.
- The cost of the unannounced audit, including travel expenses, shall be covered by the Client. Intertek will apply contractually agreed rates.
- Unannounced audits on premises of the Client's critical suppliers shall be foreseen in the contractual arrangements between the Client and its critical suppliers. The cost for an unannounced audit at a critical supplier will be charged to the Client.
- If a visa is needed to visit the country where the Client and/or the critical supplier is located, an invitation to visit the manufacturer or contracted critical supplier at any time which leaves the date of visit open shall be provided by the Client and/or its critical suppliers before the initial certification is granted.
- The Client shall permit Intertek auditors immediate access to the facilities and relevant personnel at any time during the facilities normal business hours (observing national holidays) for the purpose of performing unannounced inspections. The Client shall inform Intertek in writing if they are not able to meet this requirement on specific dates at least two (2) weeks prior. Due to the nature of unannounced audits, should the auditors turn up and no one is on site the full fee will be charged.
- Intertek will terminate the service agreement if unannounced access to the premises of the Client or his contracted critical suppliers is no longer assured.
- The Client agrees to ensure the security of Intertek auditors at all times during unannounced audits.
- Possible, requested product tests to be performed during unannounced audits are to be paid by the client. Failure to agree to these tests can lead to certificate suspension or withdrawal.

Billing Information

Travel Costs

All travel expenses (airfare, mileage, hotels, car rental, meals, etc.) will be invoiced in the amount of the actual cost incurred. Ten percent (10%) fee will automatically be added to travel expenses for the invoice process. Travel time both to and from the audit will be billed at one half day of the audit day rate stated above, per trip and per auditor.

Certificates

All certificates are provided electronically. Hard copy certificates may be provided upon request for a nominal fee.

Deposit

A deposit may be required upon an unfavorable credit report.

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Invoicing

All fees associated with the audit will be invoiced upon completion of each activity. Terms are net 30 days on invoiced amounts not covered by a deposit.

Additional Services and Audits

Additional services requested by the client and/or required to support certification will result in additional charges, invoiced at the audit-day rate stated above with travel costs as applicable OR invoiced as per current pricelist. Examples of additional services include the request for confirmation letters or other non-standard documents, translation of audit reports, reviews associated with changes to the quality management system or products and special audits resulting from such issues as not meeting the audit criteria, field complaints, product recalls, or customer reports of poor trends in quality, extensive communication related to TD assessments, delivery and/or services or related issues.

An additional visit will be required if the auditor cannot determine effectiveness during an audit.

Non-conformity review

If required, Intertek will bill a review fee of \$110 per nonconformity for offsite nonconformity review. On-site verification of nonconformities if required will be billed at the quoted daily rate. It is the client's responsibility to maintain a conforming management system. The charges only apply if nonconformities are found.

Cancellation fees

Intertek and your company will mutually agree on a date for each activity per accreditation requirements. If you cancel any of the above without a 30-day notice, Intertek will invoice for the planned costs incurred travel expenses and auditor downtime.

Disputes, Appeals, and Complaint Handling

Intertek understands the importance of impartiality and confidentiality in carrying out our certification activities. Managing conflicts of interest and ensuring objectivity are our top priorities. However, should a disagreement arise between Intertek and Company, we will handle the case in good faith and take the long-term interests of both parties into account. Our *Complaint Handling* and *Dispute and Appeals* policies are publicly available, and may be downloaded from our website at

<http://www.intertek.com/auditing/management-systems/policy/>

Next Steps

By accepting this proposal, the Client agrees to comply with the requirements specified in the following documents:

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- General Terms & Conditions (F101-4)
- Certification Agreement (F101-6)
- Medical Regulatory Certification Agreement for MDR 2017/745 (F101-6-MED-MDR)
- Medical Regulatory Certification Agreement for MDD 93/42/EEC (F101-6-MED)
- Current price list published by the Notified Body, Medical.

In addition, the client agrees for the MDSAP Program:

- To allow personnel from the Regulatory Authority, which authorized their recognition, to observe and assess Intertek's audits and to allow personnel from the Regulatory Authority access to records and documents pertaining to the manufacturer that is relevant to the audit and decision-making process upon request.
- Not to object to the make-up of audit teams. Clients can employ Intertek's disputes/appeal process to formally document any concerns related to the audit team composition after an audit team has been assigned.
- To allow MDSAP Regulatory Authorities to share all documents and records related to audits with other Regulatory Authorities that have formal established confidentiality agreements between governments which covers provisions for protecting proprietary information and trade secret information program specific conditions. To allow MDSAP Regulatory Authorities to access and share all documents and records related to audits with other Regulatory Authorities, including through the Regulatory Exchange Program (a joint global IT portal solution) with Pan American Health Organization. Such Regulatory Authorities have formal established confidentiality agreements between governments which covers provisions for protecting proprietary information and trade secret information program specific conditions.
- Not to use Intertek for consulting services at the same time as certification services. Consulting is defined as participation in designing, implementing or maintaining a management system ensuring compliance with medical device regulations covering quality management system (or good manufacturing practices), device marketing authorization and facility registration, and/or medical device adverse events and advisory notices reporting.
- That Intertek shall meet the reporting requirements of the MDSAP Program, which supersede clause 1.5 in F101-6. In particular, Intertek has the obligation to submit/report to MDSAP Regulatory Authorities:
 - Scheduled /rescheduled initial MDSAP audit or of withdrawal from MDSAP
 - All audit reports and audit findings
 - Suspension, withdrawal, cancellation, or reduction of scope
 - Perceived public health threat (complaint received about a medical device manufacturer that could indicate an issue related to the safety and effectiveness of medical devices or a public health risk (e.g. whistleblowers) or situation is found during an audit).
 - Detected fraudulent activity
 - Detected counterfeit product

This proposal becomes an agreement when all required parties have signed.

By signing this agreement, the signing company assures that the scope of certification, audit criteria, address and FTE are all correct and valid.

Any changes of above (or other reportable changes) related to the signing company, or its products, must be communicated to Intertek by filling in and sending a change notice to Intertek. Current version of change notice can be obtained from Intertek on request.

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Accepted by Biodex Medical Systems, Inc.

Name: Mary Anne Yusko

Title: Mary Anne Yusko

Date: October 13, 2022

Kara Mamakos
Accepted by Intertek Testing Services NA, Inc.

Name: Kara Mamakos

Title: Business Development Coordinator

Date: 14 October 2022

Other Intertek accredited legal entity (if applicable)

By: _____
Signature

Name: _____
Printed

Title: _____

Legal entity: _____

Date: _____

Additional resources and services to complement your business needs:

- Training Courses - <https://academy.intertek.com/>
- Business Assurance - <http://www.intertek.com/business-assurance/>
- ISO 9001 Overview - <http://www.intertek.com/auditing/iso-9001/>
- ISO 14001 Certification - <http://www.intertek.com/business-assurance/green/>
- ISO 27001 Certification - <http://www.intertek.com/auditing/iso-27001/>
- Client Testimonials - <http://www.intertek.com/business-assurance/testimonials/>

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