EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 717656**

Issued To: **GM Instruments Ltd**
Greig House
Block 1 Annickbank Innovation Campus
Annick Road
Irvine
KA11 4LF
United Kingdom

In respect of:

Manufacture of active diagnostic devices including software for Audiometry and Rhinometry
Those aspects of Annex V concerned with the metrological requirements of Rhinomanometer and Rhinospirometer

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-01-31** Date: **2020-12-18** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Supplementary Information to CE 717656

Issued To:

GM Instruments Ltd
Greig House
Block 1 Annickbank Innovation Campus
Annick Road
Irvine
KA11 4LF
United Kingdom

NBOG code(s)	Device description	Intended purpose
Class IIa		
MD 1301 MD 1111	Acoustic Rhinometer including associated standalone software	NA for class IIa devices
MD 1103 MD 1111	Audiometer including associated standalone software	NA for class IIa devices
Class Im		
MD 1301 MD 1111	Rhinomanometer including associated standalone software	NA for class Im devices
MD 1301 MD 1111	Rhinospirometer including associated standalone software	NA for class Im devices

First Issued: **2020-01-31** Date: **2020-12-18** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 717656**
Date:	**2020-12-18**
Issued To:	**GM Instruments Ltd** **Greig House** **Block 1 Annickbank Innovation Campus** **Annick Road** **Irvine** **KA11 4LF** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Advena Limited Tower Business Centre, 2nd Flr., Tower Street Swatar, BKR 4013 Malta	**EU Representative**

...making excellence a habit.™

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 717656**
Date: **2020-12-18**
Issued To: **GM Instruments Ltd**
Greig House
Block 1 Annickbank Innovation Campus
Annick Road
Irvine
KA11 4LF
United Kingdom

Date	Reference Number	Action
31 January 2020	3072153	First issue. Transfer from another notified body.
Current	3333552	Certificate Renewal. Added EU Rep 'Advena Limited.'
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
08 July 2021	3477416	Added trading name 'Accoson'

Inspiring trust for a more resilient world.

8th of July 2021

GM Instruments Ltd
Block 1 Annickbank Innovation Campus
Irvine
Annick Road
KA11 4LF
United Kingdom

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 717656	93/42/EEC Annex V	3477416	Added trading name as below. GM Instruments Ltd Also trading as Accoson

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl