DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

American Diagnostic Corporation
55 Commerce Drive
Hauppauge, New York, 11788
United States of America

23.05.2024

Notified Body Confirmation Letter

Reference: 31624353

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

American Diagnostic Corporation
55 Commerce Drive
Hauppauge, New York, 11788
United States of America

SRN Number (if available): US-MF-000021544

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided

evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Alexander Hohn
Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Aneroid Sphygmomanometers, Sub-Group Clock Aneroid Sphygmomanometers, 750W Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Clock Aneroid Sphygmomanometers, 750D Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Clock Aneroid	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sphygmomanometers, 752M Series			POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 703 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 705 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 730 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 731 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 732 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 740 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 700 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 720 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 760 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 770 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 775 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 780 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 785 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 790 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
17.05.2024	31624353-1	Initial issue
23.05.2024	31624353-2	Moved devices from table 2 to table 1
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list

AMERICAN DIAGNOSTIC CORPORATION

DECLARAȚIE DE CONFORMITATE UE Nr. 6082202
EU DECLARATION OF CONFORMITY No. 6082202

CE 1434

Producător: American Diagnostic Corporation, 55 Commerce Drive Hauppauge, NY 11788, USA
Manufacturer: American Diagnostic Corporation, 55 Commerce Drive Hauppauge, NY 11788, USA

Număr unic de înregistrare (SRN): **US-MF-000021544**
Single Registration Number (SRN): US-MF-000021544

Reprezentant autorizat în Comunitatea Europeană: SC Cattus SRL, Str. Baneasa Nr. 10 C, Targu Mures, Jud. Mures, Romania
Authorized representative in the European Community: SC Cattus SRL, Str. Baneasa Nr. 10 C, Targu Mures, Jud. Mures, Romania

Număr unic de înregistrare (SRN): RO-AR-000020096
Single Registration Number (SRN): RO-AR-000020096

Noi, American Diagnostic Corporation declarăm că prezenta declarație de conformitate este emisă sub responsabilitatea exclusivă a producătorului.
We, American Diagnostic Corporation, declare that this EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Dispozitivele acoperite de prezenta declarație sunt conforme cu Directiva 93/42/EEC a Consiliului, astfel cum a fost modificată prin 2007/47/EEC.
The devices covered by the present declaration are in conformity with Council Directive 93/42/EEC as amended by 2007/47/EEC.

Denumire dispozitiv medical *Name of the medical device*	Sphygmomanometru Aneroid Sphygmomanometer
UDI-DI	A se vedea anexa A - Codurile de produs DoC CE și revizuirea de identificare a IUD 1. Refer to Annex A- EC DoC Product Codes and UDI Identification revision 1.
Referință *Reference*	A se vedea anexa A - Codurile de produs DoC CE și revizuirea de identificare a IUD 1. Refer to Annex A- EC DoC Product Codes and UDI Identification revision 1.

Denumire comercială *Trade name*: Sphygmomanometru, Aneroid Sphygmomanometer

Scop propus *Intended purpose*: Sphygmomanometers sunt utilizate de către furnizorii de asistență medicală profesională și persoanele instruite în tehnica tensiunii arteriale auscultatory pentru a determina tensiunii arteriale sistolice și diastolice la om.

Aneroid sphygmomanometers are used by professional healthcare providers and individuals trained in the auscultatory blood pressure technique to determine systolic and diastolic blood pressure in humans.

AMERICAN DIAGNOSTIC CORPORATION

Cod EMDN *EMDN code*:	C9006
Clasa de risc *Risk class*:	Clasa Im, regula 1; Class Im, Rule 1
Specificații comune *Common Specifications*:	Nu este cazul, Not applicble
Organism notificat *Notified Body*:	Polskie Centrum Badań i Certyfikacji S.A./ Polish Centre for Testing and Certification Notified Body No. 1434 469 Puławska Street, 02-844 Warsaw www.pcbc.gov.pl Medical Devices Certification Division
Procedura de evaluare a conformității, *Conformity assessment procedure*:	Anexa V și anexa VII la Directiva 93/42/EEC a Consiliului, astfel cum a fost modificată prin 2007/47/EEC Annex V and Annex VII of Council Directive 93/42/EEC as amended by 2007/47/EEC
Certificat de conformitate UE *EU certificate of conformity*	1434-MDD-371/2021

Semnat pentru și în numele American Diagnostic Corporation, New-York, 1/19/23
Signed for and on behalf of American Diagnostic Corporation, New-York 1/19/23

Semnatar autorizat *Authorized signature*

Ștampila *Stamp*

Revision Control Table				
Rev #:	Rev Date:	Revision History Filename:	Creator:	Approver:
6	1/7/21	Revision History EC Declaration of Conformity TEMPLATE rev.6	K. Silk	M. Falco
7	4/20/21	EC Declaration of Conformity Template, Rev 6 to 7	M. Falco	K. Silk
8	8/31/21	EC Declaration of Conformity Template, Rev 7 to 8	M. Falco	K. Silk
9	12/16/21	EC Declaration of Conformity Template, Rev 8 to 9	M. Falco	C. Campbell

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-371/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Aneroid Sphygmomanometers	Clock Aneroid Sphygmomanometers	750W Series
		750D Series
		752M Series
	Palm Aneroid Sphygmomanometers	703 Series
		705 Series
		730 Series
		731 Series
		732 Series
		740 Series
	Pocket Aneroid Sphygmomanometers	700 Series
		720 Series
		760 Series
		770 Series
		775 Series
		780 Series
		785 Series
		790 Series

CE 1434

Issued under the Contract No. 8/18/2020
Application No: 165/2020
Certificate bears the qualified signature.
Warsaw, 21/05/2021

Vice-President

CERTIFICATE

EC Certificate No. 1434-MDD-371/2021

Production Quality Assurance
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

American Diagnostic Corporation

55 Commerce Drive
Hauppauge
NY 11788 UNITED STATES

for manufacture and final inspection of medical devices, class I with a measuring function

Aneroid Sphygmomanometers

The list of medical devices covered by this certificate is provided in the annex 1

complies with requirements
of Annex V to Directive 93/42/EEC (as amended) implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 21.05.2021 to 26.05.2024

The date of issue of the Certificate: 21.05.2021

The date of the first issue of the Certificate: 21.05.2021

CE 1434

Issued under the Contract No. 8/18/2020
Application No: 165/2020
Certificate bears the qualified signature.
Warsaw, 21/05/2021
Module D1/2/3/4

Vice-President

FBM-27-E_9