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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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. 6082201
EU DECLARATION OF CONFORMITY No. 6082201

CE

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 Regulamentul (UE) 2017/745.
The devices covered by the present declaration are in conformity with Regulation (EU) 2017/745.

Denumire dispozitiv medical *Name of the medical device*	stetoscop Stethoscope
UDI-DI	A se vedea anexa A - Codurile de produs DoC CE și revizuirea de identificare a IUD 2. Refer to Annex A- EC DoC Product Codes and UDI Identification revision 2.
Referință *Reference*	600 Series, 601 Series, 602 Series, 603 Series, 604 Series, 605 Series, 606 Series, 607 Series, 608 Series, 612 Series, 613 Series, 614 Series, 615 Series, 618 Series, 619 Series, 641 Series, 645 Series, 646 Series, 647 Series, 660 Series, 663 Series, 665 Series, 670 Series, 672 Series

Denumire comercială *Trade name*: stetoscop
Stethoscope

Scop propus *Intended purpose*: Stetoscopul este destinat să fie utilizat pentru a asculta sunete pulmonare și cardiovasculare, precum și auscultare. Stetoscoapele pot fi utilizate singure sau împreună cu un sphygmomanometru.

AMERICAN DIAGNOSTIC CORPORATION

The stethoscope is intended to be used to listen to pulmonary and cardiovascular sounds as well as auscultation. Stethoscopes can be used alone or in conjunction with a sphygmomanometer.

Cod EMDN *EMDN code*:	C9005
Clasa de risc *Risk class*:	Clasa I, Regula 1, Class I, Rule 1
Specificații comune *Common Specifications*:	Nu este cazul, Not applicble
Organism notificat *Notified Body*:	Nu este cazul, Not applicble
Procedura de evaluare a conformității *Conformity assessment procedure*:	Art. 52(7) & Anexa IV (Declarația de conformitate), conform Regulamentului (UE) 2017/745 (MDR) *Art 52(7) & Annex IV (Declaration of Conformity), according Regulation (EU) 217/745 (MDR)*
Certificat de conformitate UE *EU certificate of conformity*	Nu este cazul, Not applicble

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	K. Silk