



EU DECLARATION OF CONFORMITY No. 6082201



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

Single Registration Number (SRN): US-MF-000021544

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

Single Registration Number (SRN): RO-AR-000020096

We, American Diagnostic Corporation, declare that this EU declaration of conformity is issued under the sole responsibility of the manufacturer.

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

Table with 2 columns: Name of the medical device, UDI-DI, Reference and Stethoscope, Refer to Annex A- EC DoC Product Codes and UDI Identification revision 2., 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

Trade name: Stethoscope

Intended purpose: 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.

EMDN code: C9005

Risk class: Class I, Rule 1

Common Specifications: Not applicable

Notified Body: Not applicable

Conformity assessment procedure: Art 52(7) & Annex IV (Declaration of Conformity), according Regulation (EU) 217/745 (MDR)

EU certificate of conformity: Not applicable



Signed for and on behalf of American Diagnostic Corporation, New-York 3/14/24

  
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 Authorized signature

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