EC DECLARATION OF CONFORMITY

APPLICATION OF MEDICAL DEVICE DIRECTIVE

: Annex II excluding section 4 93/42/EEC, as amended by Directive

2007/47/EC

RoHS Directive 2011/65/EU, along with

Annex IV, item 1 (b) exemption

STANDARDS TO WHICH CONFORMITY IS DECLARED

: EN 60601-1 3.1 Edition EN60601-1-2; EN 14971

EN60601-1-6; EN ISO 80601-2-55

MANUFACTURER'S NAME

: TELEDYNE INSTRUMENTS ANALYTICAL INSTRUMENTS

a business unit of Teledyne Instruments, Inc.

MANUFACTURER'S ADDRESS

: 16830 Chestnut Street

City of Industry, CA 91748

U.S.A.

PRODUCT NAME

: Oxygen Analyzer

DEVICE CLASSIFICATION

: Class IIa (Annex IX, Rule 10)

MODEL NUMBER

: AX300 and AX300-I

Authorized Representative

: Viamed Limited

15 Station Road, Cross Hills Kieghley. W. Yorkshire BD20 7DT United Kingdom

Ph: + 44 (0) 1535 634542 URL: <u>www.viamed.co.uk</u>

Registration Information

NB: BSI Netherlands /# 2797

CE Certification # CE 02000

We, Teledyne Analytical Instruments, a business unit of Teledyne Instruments, Inc, declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC, as amended by Council Directive 2007/47/EC, for Medical Devices.

SIGNATURE:_A

FULL NAME: Roger Starlin

POSITION: Manager, Quality Assurance

Date: 9-12-19

SIGNATURE:

FULL NAME: Angel Alegria

POSITION: New Products Manager

Date: 9-12-