## **DECLARATION OF CONFORMITY**



APPLICATION OF MEDICAL DEVICE DIRECTIVE

: 93-42/EEC (Annex II)

EN46001 ISO13485 ISO9001:2000

STANDARDS TO WHICH CONFORMITY IS DECLARED : ISO 7767

IEC/EN60601-1, IEC/EN60601-1-2

EN61000-4-2,3,4,6,8.

MANUFACTURER'S NAME

: TELEDYNE INSTRUMENTS ANALYTICAL INSTRUMENTS

MANUFACTURER'S ADDRESS : 16830 Chestnut Street

City of Industry, CA 91748-1020

U.S.A.

**EQUIPMENT TYPE** 

: Medical Device, Oxygen Analyzer & Monitor

EQUIPMENT CLASSIFICATION: Class IIa (Annex IX, Rule 10)

MODEL NUMBER

: AX300 & MX300

THE UNDERSIGNED HEREBY DECLARE THAT THE EQUIPMENT SPECIFIED ABOVE CONFORMS TO THE ABOVE DIRECTIVE(S) AND STANDARD(S).

SIGNATURE:

FULL NAME: Ray Khajavi

POSITION: Director, Quality Assurance

DATE: 02/26/03

PLACE: City of Industry, California