

Teledyne Analytical Instruments  
16830 Chestnut Street,  
City of Industry,  
California, 91749,  
United States

25 May 2024

**Notified Body Confirmation Letter**  
**Reference: CN00449-01-001**

To whom it may concern,

Certificates included:  
MDD EC Certificate Annex II, CE02000 (NB2797)  
See attached tables for details of devices.

**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, Intertek Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2862 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:

Teledyne Analytical Instruments  
16830 Chestnut Street,  
City of Industry,  
California, 91749,  
United States

SRN Number (if available): Not known

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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



Brian Mather  
Certification Manager  
Intertek Medical Notified Body AB

**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:**

<b>MDD/AIMDD Device name or REF</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the MDD/AIMDD device</b>
Oxygen Sensor Class C1	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class C1R	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class C2R	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R13	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R-15	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R-17MED	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R-22MED	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R23	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R24MED	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R26MED	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R-29MED	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R-29IMED	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R-30MED	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R-34MED	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class R-36MED	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class T-1	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class T-2	Class IIa	NA	CE02000 NB2797

Oxygen Sensor Class T-4	Class IIa	NA	CE02000 NB2797
Oxygen Sensor Class T-7	Class IIa	NA	CE02000 NB2797
Ultra Fast Oxygen Sensor Class UFO-130	Class IIa	NA	CE02000 NB2797
Ultra Fast Oxygen Sensor Class UFO-130-2	Class IIa	NA	CE02000 NB2797

**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

**Confirmation Letter Revision History**

Date	NB internal reference traceable to each version of the letter	Action
25 May 2024	CN00449-01	Initial Issue
29 May 2024	CN00449-01-01	Addition of device

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 02000  
**Issued To:** **Teledyne Analytical Instruments**  
**A business unit of Teledyne**  
**Instruments, Inc**  
**16830 Chestnut Street**  
**City of Industry**  
**California**  
**91748**  
**USA**

In respect of:

**The design and manufacture of oxygen sensors**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1998-07-09**

Date: **2021-02-03**

Expiry Date: **2023-07-08**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 02000

Issued To:

**Teledyne Analytical Instruments**  
**A business unit of Teledyne**  
**Instruments, Inc**  
**16830 Chestnut Street**  
**City of Industry**  
**California**  
**91748**  
**USA**

NBOG code(s)	Device description	Intended purpose
<b>Class IIa</b>		
MD 1102	Oxygen Sensors	N/A, for class IIa

First Issued: **1998-07-09**

Date: **2021-02-03**

Expiry Date: **2023-07-08**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.