



Steve Nixon <steve.nixon.viamed@googlemail.com>

MHRA Device Registrations Service - Device Registration action required - Conformity Assessment Document Expiry [Teledyne Analytical Instruments]

1 message

No Reply <no-reply@mhra.gov.uk>
 To: steve.nixon@viamed.co.uk

9 July 2023 at 02:15

Dear Customer,

UK Responsible Person name and address:

Viamed Limited
 15 Station Road
 Cross Hills
 Keighley
 West Yorkshire
 BD20 7DT
 England, United Kingdom

Manufacturer name and address:

Teledyne Analytical Instruments
 Teledyne Instruments Inc.
[16830 Chestnut Street](#)
 City of Industry
 California
 91748-1020
 United States

The following Conformity Assessment document(s) have expired:

| Document Type | Reference | Expiry Date | UK Approved Body/EU Notified Body | Conformity Assessment Route |
|---|-----------|-------------|-----------------------------------|-----------------------------|
| Full Quality Assurance (Annex II excluding Section 4) | CE 02000 | 08/07/2023 | BSI Assurance UK Ltd | CE - MDD/IVDD/AIMD |

All devices and products linked to the above documents are no longer actively registered with MHRA. You will not be able to order [Certificates of Free Sale](#) for them until Conformity Assessment documents have been updated in the registration system.

The GMDN term for the devices will remain on the [Public Access Registration Database \(PARD\)](#) with the following wording appended 'Conformity Assessment Certificate expired', until they are updated. Where a conformity assessment certificate is listed as expired, existing products already placed on the market prior to the expiry may not be affected by this expiry and can continue to be used. This expiry stops new products being placed on the market until there is a new certificate of conformity.

Update your Conformity Assessment documents or remove the devices permanently from your registration, please follow the step by step instructions in the [Device Registration Reference Guide](#) and [video tutorials](#)

You will not lawfully be able to place devices with expired conformity assessment certificates on the market given it is a legal requirement to hold an active registration with the UK competent authority (MHRA). It is an offence to place a non-compliant device on the market in the UK. See our [medical device regulation](#) guidance.

Please do not respond directly to this email address. The originating email account is not monitored.

Yours sincerely,

Device Registrations service
 Devices division
 MHRA
[10 South Colonnade, Canary Wharf, London, E14 4PU](#)
device.registrations@mhra.gov.uk

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