Gmail

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> 9 July 2023 at 02:15
To: steve.nixon@viamed.co.uk

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-complaint 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