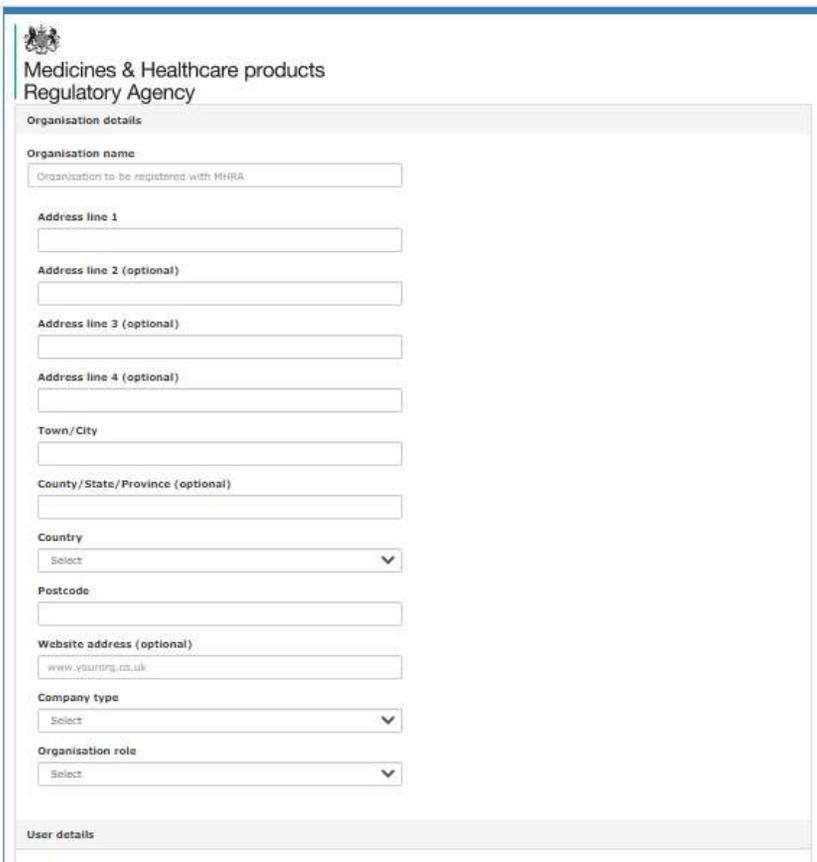


STEP One if you do not already have an account:

You need to create an account on the [MHRA DORS](https://mhrabpm.appiancloud.com/suite/plugins/servlet/registration) before you can start registering your devices

<https://mhrabpm.appiancloud.com/suite/plugins/servlet/registration>



The screenshot shows the registration form for the Medicines & Healthcare products Regulatory Agency. The form is titled "Medicines & Healthcare products Regulatory Agency" and is divided into two main sections: "Organisation details" and "User details".

Organisation details

- Organisation name:** A text input field with the placeholder "Organisation to be registered with MHRA".
- Address line 1:** A text input field.
- Address line 2 (optional):** A text input field.
- Address line 3 (optional):** A text input field.
- Address line 4 (optional):** A text input field.
- Town/City:** A text input field.
- County/State/Province (optional):** A text input field.
- Country:** A dropdown menu with "Select" as the current selection.
- Postcode:** A text input field.
- Website address (optional):** A text input field with the placeholder "www.yourorg.co.uk".
- Company type:** A dropdown menu with "Select" as the current selection.
- Organisation role:** A dropdown menu with "Select" as the current selection.

User details

The "User details" section is partially visible at the bottom of the form.

Once completed it can take around 5 working days to receive a response. Which will contain a link and temporary password.

[Log into MHRA DORS](#)

ALPHA Release This is a new service - your feedback will help improve it



Welcome, ANDREW SANDERS

[Reference Guides](#)

[Help & Contact](#)

Device Registrations & Certificates of Free Sale service for medical devices

Register your devices and products with MHRA. Purchase Certificates of Free Sale (CFS) for medical devices to export medical devices outside the UK if required by other countries. This service is only available to GB based manufacturers and UK Responsible Person of non-UK manufacturers.

ENTER ►





Click Enter



Device Registrations & Certificates of Free Sale service for medical devices

Register your devices and products with MHRA. Purchase Certificates of Free Sale (CFS) for medical devices to export medical devices outside the UK if required by other countries. This service is only available to GB based manufacturers and UK Responsible Person of non-UK manufacturers.

ENTER ▶





Click on your name



Device Registration & Certificates of Free Sale

Your Organisation

Name	Address	Country	Devices (Products)	Registration Status
Andy Sanders	The Barn down the lane and round the corner	England, United Kingdom	0 (0)	<input type="radio"/>

Key

Registered
 Not Registered
 Unregistered
 Suspended
 Rejected

Manufacturers you represent

Only registered manufacturers appear here. Newly submitted and draft manufacturers can be found from the **Applications** list.

[ADD NEW MANUFACTURER](#)

You have no registered manufacturers.

Click the **Add New Manufacturer** button to add manufacturers you represent, register devices on their behalf and order Certificates of Free Sale, if required. This service is only available to UK Responsible Person of non-UK manufacturers.

1) Check your details



2) Click Add devices

Summary

! Your registration with the MHRA must be reviewed and renewed one year after the anniversary date and every two years subsequently. The anniversary date is determined by the date your account was created with the MHRA. Your Registration Renewal is 02/02/2023. Failure to renew your registration will result in your account being suspended. A suspended account means you will not be able to place new devices on the market given it is a legal requirement to hold an active registration with the competent authority (MHRA). It is an offence to place a non-compliant device on the market in the UK.

Basic Information

Account Number 0000022632
EU Single Registration Number (SRN)
Role / Account Type Assembler
Company Type Other
VAT Number N/A
Created Date 02 February 2022

Registration Status Not Registered
PARD Options

- Publish Organisation's Name
- Publish Organisation's Address

Company Registration Number N/A
Registered under 2017 MDRs No

Organisation Details

Registered Address The Barn
down the lane
and
round the corner
PR6
England UK

Telephone 07768*****
Fax N/A
Website N/A

Contact Details

Full Name ANDREW SANDERS
Job Title

Email Sanders@freeserve.AOL.co.uk
Telephone 07768*****

Customer Service Contact

Telephone No.

Email Address

Add New Devices for Andy Sanders - TEMP20220307142657

Manufacturer

Device

Self-certification conformity
declarations

Products

Review

Payment

Select:
General Medical Device



Declare devices

What type of device is it?

- General Medical Device
- In Vitro Diagnostic Device
- Active Implantable device (Directive 90/385/EEC only)
- System or Procedure Pack

GMDN Code/Term

[View all GMDN terms and definitions](#)

CONTINUE

SAVE & EXIT

DELETE APPLICATION

Add New Devices for Andy Sanders - TEMP20220307142657

Manufacturer	Device	Self-certification conformity declarations	Products	Review	Payment
--------------	--------	--	----------	--------	---------

Declare devices

What type of device is it?

- General Medical Device
- In Vitro Diagnostic Device
- Active implantable device (Directive 90/385/EEC only)
- System or Procedure Pack

GMDN Code/Term

Prescription spectacles

Term name	↑
65693 - Colour discrimination non-prescription spectacles	
65694 - Colour discrimination prescription spectacles	
35065 - Prescription spectacles	

[View all GMDN terms and definitions](#)

CONTINUE SAVE & EXIT

DELETE APPLICATION

Enter: Prescription Spectacles
The drop down box appears
Click on 35065
- Prescription Spectacles

Add New Devices for Andy Sanders - TEMP20220307142657

Manufacturer Device Self-certification conformity declarations Products Review Payment

Declare devices

What type of device is it?

- General Medical Device
- In Vitro Diagnostic Device
- Active implantable device (Directive 90/385/EEC only)
- System or Procedure Pack

GMDN Code/Term

35065 - Prescription spectacles

[View all GMDN terms and definitions](#)

Is it custom made?

- Yes
- No

What risk classification applies to this device?

- Class I
- Class IIa
- Class IIb
- Class III

[Click here to know about risk classification.](#)

Which directive/regulation does this device comply with?

- Directive 93/42/EEC
- European medical devices regulations EU 2017/745

 MHRA will only accept registrations for sterile and/or measuring Class I and all Class IIa, IIb and III devices under (EU)2017/745 if the EU Notified Body is designated under the EU Medical Devices Regulation 2017/745.

Device labelled as sterile?

- Yes
- No

Single-use device?

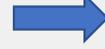
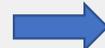
- Yes
- No

Maximum number of reuses (if applicable)

Is it intended for single patient use? (optional)

--Please Select--

Click all mandatory sections as shown



Continued from previous page

Click all mandatory sections as shown



Reprocessed single-use device?

Yes

No

Are any of the products related to this device active?

Yes

No

Device intended to administer and/or remove medicinal product?

Yes

No

Are any of the products related to this device measuring?

Yes

No

Basic UDI-DI Issuing Entity(optional)

--Please Select--

Presence of a substance which, if used separately, may be considered to be a medicinal/herbal medicinal product (optional) ⓘ

--Please Select--

Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma (optional) ⓘ

--Please Select--

Has a Clinical investigation been conducted? (optional)

--Please Select--

CONTINUE

SAVE & EXIT

DELETE APPLICATION

Click continue



Add New Devices for Andy Sanders - TEMP20220307142657

Manufacturer

Device

Self-certification conformity declarations

Products

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Self-certification conformity declarations

- **Declaration of Conformity** - Class I medical devices that do not require certification by a UK Approved Body or EU Notified Body i.e. non-sterile, non-measuring, non-reprocessed. General IVD medical devices that do not require certification by a UK Approved Body or EU Notified Body.
- **Custom-Made Statement** - All custom-made devices.
- **Declaration for all system or procedure packs and assemblers** - to UK MDR 2002 Regulation 14 (Article 12 of Directive 93/42/EEC) or Article 22 of EU Regulation 2017/745.
- **Declaration for Performance Evaluation** - to UK MDR 2002 Regulation 43 Statement (Annex VIII of Directive 98/79/EC) or Part A of Annex XIII of EU regulation 2017/746.

Medical Devices Directive 93/42 EEC & Medical Devices Regulation (EU) 2017/745

Upload a new Self-certification conformity declaration

UPLOAD  Drop file here

File size limit should not exceed 15MB. Only the following file formats are acceptable: .doc, .docx, .pdf, .jpg, .tif, .png, .odt

We may request further technical documentation from you that demonstrates your products conform to the requirements of the Medical Device Regulations. If you fail to co-operate with our requests we will consider using our enforcement powers.

Conformity assessment

Please select 

If you are providing Self-certification conformity declarations for CE marked devices, you must ensure that you have appointed an EU Authorised Representative (EC Rep) in one of the EU 27 countries or in Northern Ireland

Find out more about [Declaration of Conformity](#) / [Custom made statement](#) / [UK MDR 2002 Regulation 14](#) / [Performance Evaluation](#) / [EU regulations](#)

Document Reference

UPLOAD DOCUMENT

UPLOAD your declaration of conformity sample attached

CONTINUE

SAVE & EXIT

BACK

DELETE APPLICATION

Add New Devices for Andy Sanders - TEMP20220307142657

Manufacturer	Device	Self-certification conformity declarations	Products	Review	Payment
--------------	--------	--	----------	--------	---------

Self-certification conformity declarations

- **Declaration of Conformity** – Class I medical devices that do not require certification by a UK Approved Body or EU Notified Body i.e. non-sterile, non-measuring, non-reprocessed. General IVD medical devices that do not require certification by a UK Approved Body or EU Notified Body.
- **Custom-Made Statement** – All custom-made devices.
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Medical Devices Directive 93/42 EEC & Medical Devices Regulation (EU) 2017/745

Upload a new Self-certification conformity declaration

 **SAMPLE DECLARATION OF CONFORMITY GB - Ex NI**
DOCX - 14.43 KB

File size limit should not exceed 15MB. Only the following file formats are acceptable: .doc, .docx, .pdf, .jpg, .tif, .png, .odt

We may request further technical documentation from you that demonstrates your products conform to the requirements of the Medical Device Regulations. If you fail to co-operate with our requests we will consider using our enforcement powers.

Conformity assessment

Please select

Please select

- CE - MDD/IVDD/AIMD
- UKCA - MDD/IVDD/AIMD
- CE(UK NI) - MDD/IVDD/AIMD



UPLOAD DOCUMENT

CONTINUE SAVE & EXIT BACK

DELETE APPLICATION

- **Declaration of Conformity** – Class I medical devices that do not require certification by a UK Approved Body or EU Notified Body i.e. non-sterile, non-measuring, non-reprocessed. General IVD medical devices that do not require certification by a UK Approved Body or EU Notified Body.
- **Custom-Made Statement** – All custom-made devices.
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- **Declaration for Performance Evaluation** – to UK MDR 2002 Regulation 43 Statement (Annex VIII of Directive 98/79/EC) or Part A of Annex XIII of EU regulation 2017/746.

Medical Devices Directive 93/42 EEC & Medical Devices Regulation (EU) 2017/745

Select from existing Self-certification conformity declarations

<input checked="" type="checkbox"/> Filename	Document Reference	Conformity Assessment Type	
<input checked="" type="checkbox"/> Declaration of conformity statement	Dec of conformity	UKCA - MDD/IVDD/AIMD	x

Upload a new Self-certification conformity declaration

File size limit should not exceed 15MB. Only the following file formats are acceptable: .doc, .docx, .pdf, .jpg, .tif, .png, .odt

Filename must not contain any special characters other than hyphen (-) or underscore (_).

We may request further technical documentation from you that demonstrates your products conform to the requirements of the Medical Device Regulations. If you fail to co-operate with our requests we will consider using our enforcement powers.

Conformity assessment

If you are providing Self-certification conformity declarations for CE marked devices, you must ensure that you have appointed an EU Authorised Representative (EC Rep) in one of the EU 27 countries or in Northern Ireland

Find out more about [Declaration of Conformity](#) / [Custom made statement](#) / [UK MDR 2002 Regulation 14](#) / [Performance Evaluation](#) / [EU regulations](#)

Document Reference

Reference must not contain any special characters other than hyphen (-) or underscore (_).



Add New Devices for Andy Sanders - TEMP20220307142657

Manufacturer

Device

Self-certification conformity
declarations

Products

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Payment

Add products

Here you can add product information for the device:

35065-Prescription spectacles

You need to provide medical device name, model/version and catalogue/reference for each product. Product information follows guidelines set by the International Medical Device Regulators Forum in their document [Common Data Elements for Medical Device Identification](#).

Add products one by one

Medical Device Name (Brand/Trade/Proprietary or Common name)

A name used to assist in the identification of the regulated medical device. It can be a brand, trade, proprietary or common name.

Prescription Spectacles

Is Model/Version applicable?

No

Model/Version

The value used to represent one medical device or a family of devices to group many variations that have shared characteristics. If you have not allocated a model/version select 'No' for 'Is Model/Version applicable?' question.

Not Applicable

Is Catalogue/Reference applicable?

Yes

Catalogue/Reference (REF)

The value given by the Regulated Entity to identify the specific medical device as it relates to its form/fit, function and process. The value should apply to one specific medical device only within that Regulated Entity's device range. Catalogue/Reference is sometimes referred to by other terms such as SKU (Stock Keeping Unit). If you have not allocated a Catalogue/Reference select 'No' for 'Is Catalogue/Reference applicable?' question.

35065

Add products in bulk

You can also upload product information in bulk using our template. This is how

1. Download our product template-always download a new template to ensure you have the latest version.
2. Enable editing and/or content on the template.
3. Populate the template with your product information.
4. Do not paste formulas from other Excel documents and ensure text does not exceed maximum length specified for each field.
5. Ensure 'Ready to validate' message appears on the template.
6. Click for primary validation and correct any errors identified.
7. Ensure 'Ready for upload and validation. The validation will fail if you have not completed the template correctly.' message appears on the template.
8. Upload your completed template using the "upload" button below.
9. Click the Confirm Bulk Upload and Preview products button (below) - limited preview will be available - ensure all fields are correct in the template.
10. If secondary validations fails, you will see an error message indicating which columns in the template require attention.

UPLOAD

Drop file here

CONFIRM BULK UPLOAD AND PREVIEW PRODUCTS

Enter details
as shown for
prescription
spectacles

Prescription Spectacles

No

Yes

35065

Next are optional fields

UDI Issuing Entity (optional) ⓘ

GS1 AISBL
 HIBCC
 ICCBBA
 IFA GmbH
 UDI not assigned

Product Status ⓘ

On the GB & NI market

URL for additional information (optional) ⓘ

Type of UDI-PI (optional) ⓘ

Lot or Batch Number
 Serial Number
 Manufacturing date
 Expiration date
 Software version

Does the device incorporate human cells or tissues, or their derivatives (optional)

---Please Select---

Does the device incorporate animal cells or tissues, or their derivatives (optional)

---Please Select---

Are storage/handling conditions specified in the label/instructions for use (optional)

---Please Select---

Quantity per package configuration (optional)

Need for sterilisation before use (optional) ⓘ

---Please Select---

What MRI safety information does the labelling contain? (optional)

---Please Select---

Does the label/instruction for use include Critical warnings or contra-indications (optional)

---Please Select---

Containing latex (optional)

---Please Select---

Clinical size applicable (optional) ⓘ

---Please Select---

UDI-DI from secondary entity (optional) ⓘ

---Please Select---

Endocrine disruptor (optional) ⓘ

---Please Select---

Additional product description (optional) ⓘ

These are optional fields

Click



ADD PRODUCT

10 per page ▾

Product preview (products: 1)

Preview only displays limited fields

Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status	
Prescription Spectacles	Not Applicable	35065			On the GB & NI market	✕

Click



CONTINUE

SAVE & EXIT

BACK

DELETE APPLICATION

Add New Devices - TEMP20220307142657

Manufacturer

Device

Self-certification conformity
declarations

Products

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Payment

Review

Devices

> 35065 - Prescription spectacles

ADD ANOTHER DEVICE

You are about to register/update an existing registration as (or on behalf of) a manufacturer or an assembler of systems and/or procedure packs. Before applying the UKCA/CE mark to medical devices or placing them on the market in the UK the manufacturer must provide a signed Self-certification conformity declaration stating that each medical device has met the appropriate essential requirements (or general safety and performance requirements, where applicable) of the relevant medical devices legislation, including the availability of technical and clinical data for each device. Devices requiring conformity assessments to be carried out by a UK approved body/ EU notified body must provide a valid UKCA/CE certificate. There are also additional legal requirements which must be met, including those which assemblers of systems and procedure packs specifically should ensure they meet before marketing such products.

Further information on the legal requirements is available at the following links in relation to the [UK Medical Devices Regulations 2002](#) (in the form that they exist on 1 January 2021) and also regarding the [EU Medical devices and in-vitro diagnostic devices regulations](#).

Failure to declare compliance with the directive/regulation that you are certified for will result in your registration becoming invalid and you will be charged a further £100 to make the relevant changes.

NOTE: It is possible to select a GMDN code/term for a product that is not categorised as a medical device under medical devices legislation in the UK. Manufacturers are responsible for correctly classifying their devices and ensuring they are compliant with the relevant legislation. MHRA have the right to remove registrations, both organisations and or their devices, if we consider that the registered products are not medical devices, are incorrectly classified or if they do not comply with the relevant legislation. Under such circumstances, the £100 fee is non-refundable.

Please tick to confirm you have read and understood the above requirements and that you agree to our [terms and conditions](#).

I have read and agree to the terms and conditions

CONTINUE

SAVE & EXIT

BACK

DELETE APPLICATION

Read T and Cs
and confirm



Click



Check details and Pay

Add New Devices - TEMP20220307142657

Manufacturer Details

Device Details

Review

Payment

Choose a Billing address and then related payment method. See instructions below on how to add a new Billing address if required.

Payment details

Devices Fee : £100.00

Total: £100.00

Address details

Choose Billing Address

The Barn down the lane and round

Please choose a Billing Address matching your payment card.

The Barn down the lane and round the corner

PR6

England UK

i You can add other addresses by going to 'Manage Other Addresses' in your organisation's 'Related Actions' tab.

Remember to 'Save and Exit' to keep the information already entered if you move away from this screen

[Click here](#) to download the Proforma.

You can click above if you require a pro-forma invoice to complete a BACS/CHAPS payment. (You can save your application using the save and exit option below if you are not yet ready to complete payment)

Payment method

Choose payment method



SUBMIT APPLICATION

SAVE AND EXIT

BACK

DELETE APPLICATION