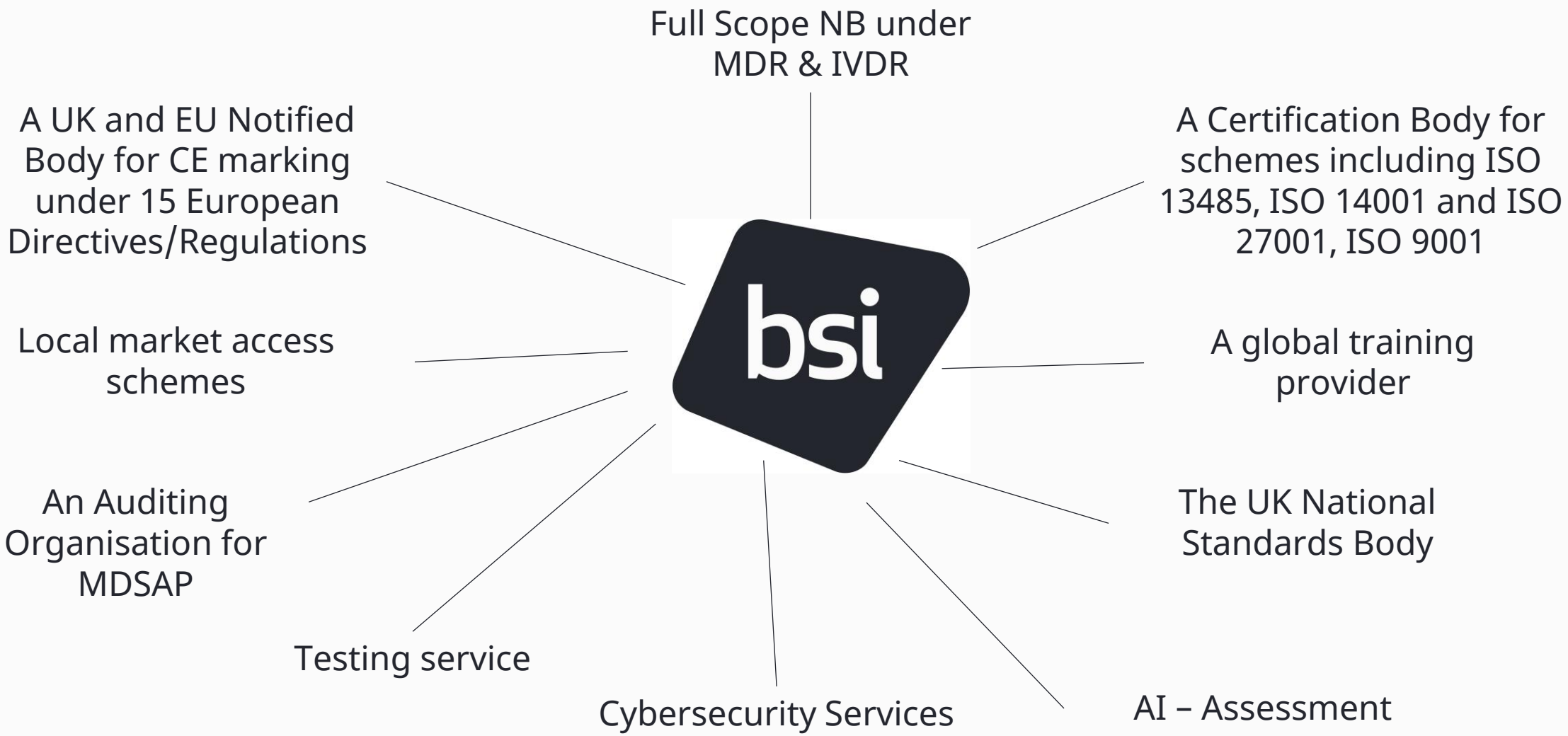
Navigating your IVDR application: How to work with a Notified Body - Webinar

Presented by Charlotte Hess
Senior Business Development Manager IVD EMEA North

BSI at a glance



Poll Question

About BSI Regulatory Services (Medical Devices)

96%	**96% of the world's top 25** medical device manufacturers work with BSI
1000+	**Over 1000** colleagues worldwide
Market leader	**Largest Notified Body** globally; BSI is a market leader
Full scope Notified Body	**Designated with full scope** IVDR and MDR
Designated and Accredited	**Designated by** MHRA (0086) and IGJ (2797) **Accredited by** UKAS and RvA **Recognized by** MHLW/PMDA, TFDA, MDB, INMETRO, MDSAP RAs

BSI Medical Devices – Technical expertise

We have over 380+ Technical Specialists

Our team has over 4.000 years combines regulatory, industry and academic experience

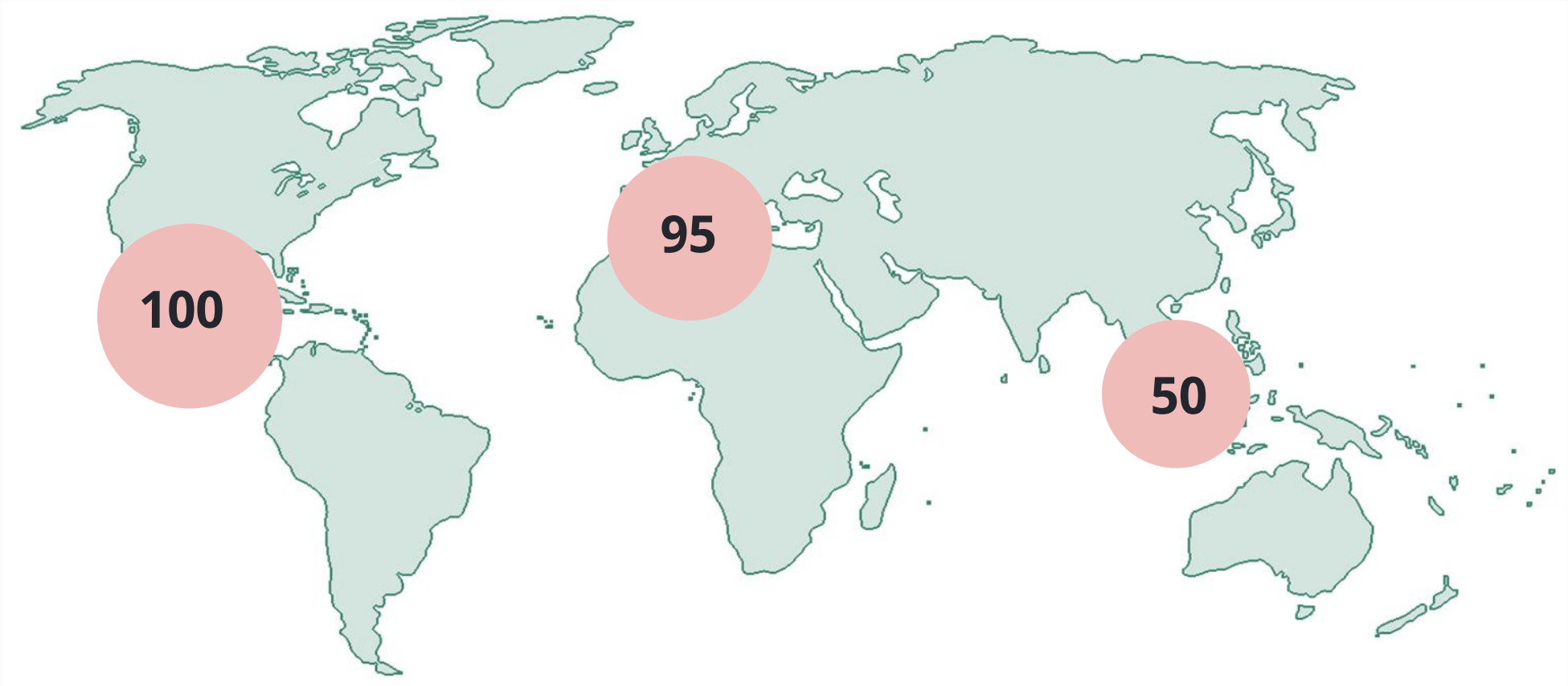
Our team are based across the globe and speak 25 different languages

We work with external experts including clinicians, biostatisticians, toxicologists and software experts

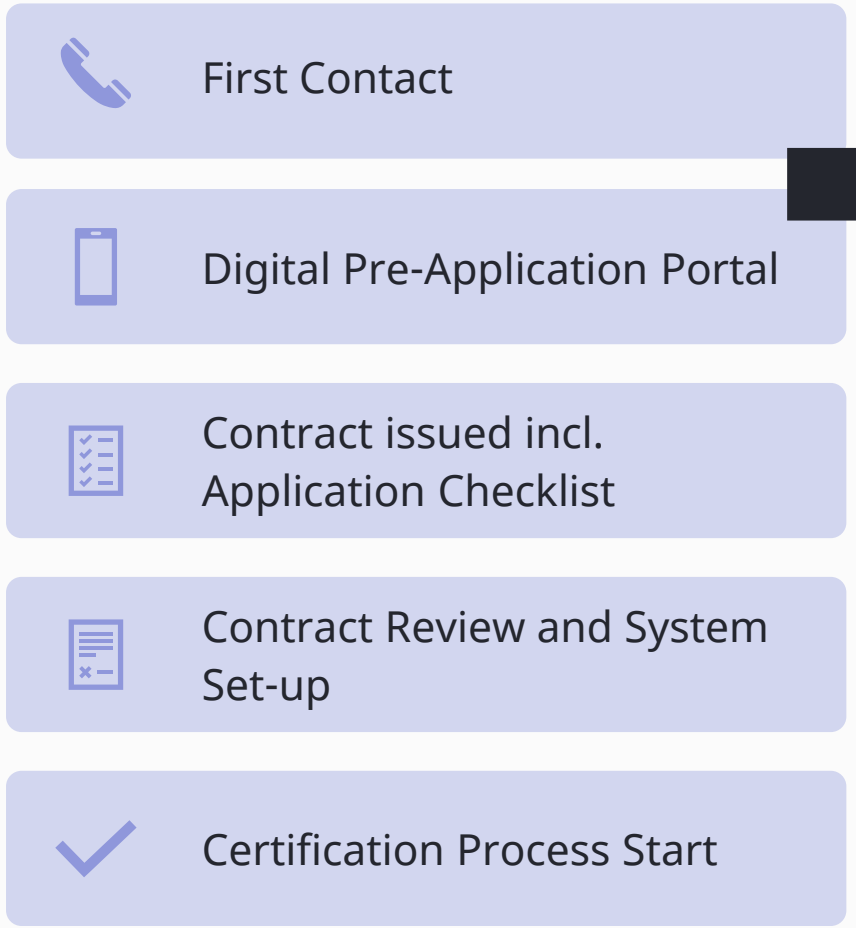
We have a team of in-house clinicians and have in-house specialists with expertise in biological substances, medicinal substances and microbiology

BSI Medical Devices – QMS expertise

The BSI QMS team includes 245 auditors worldwide



Application Process Overview

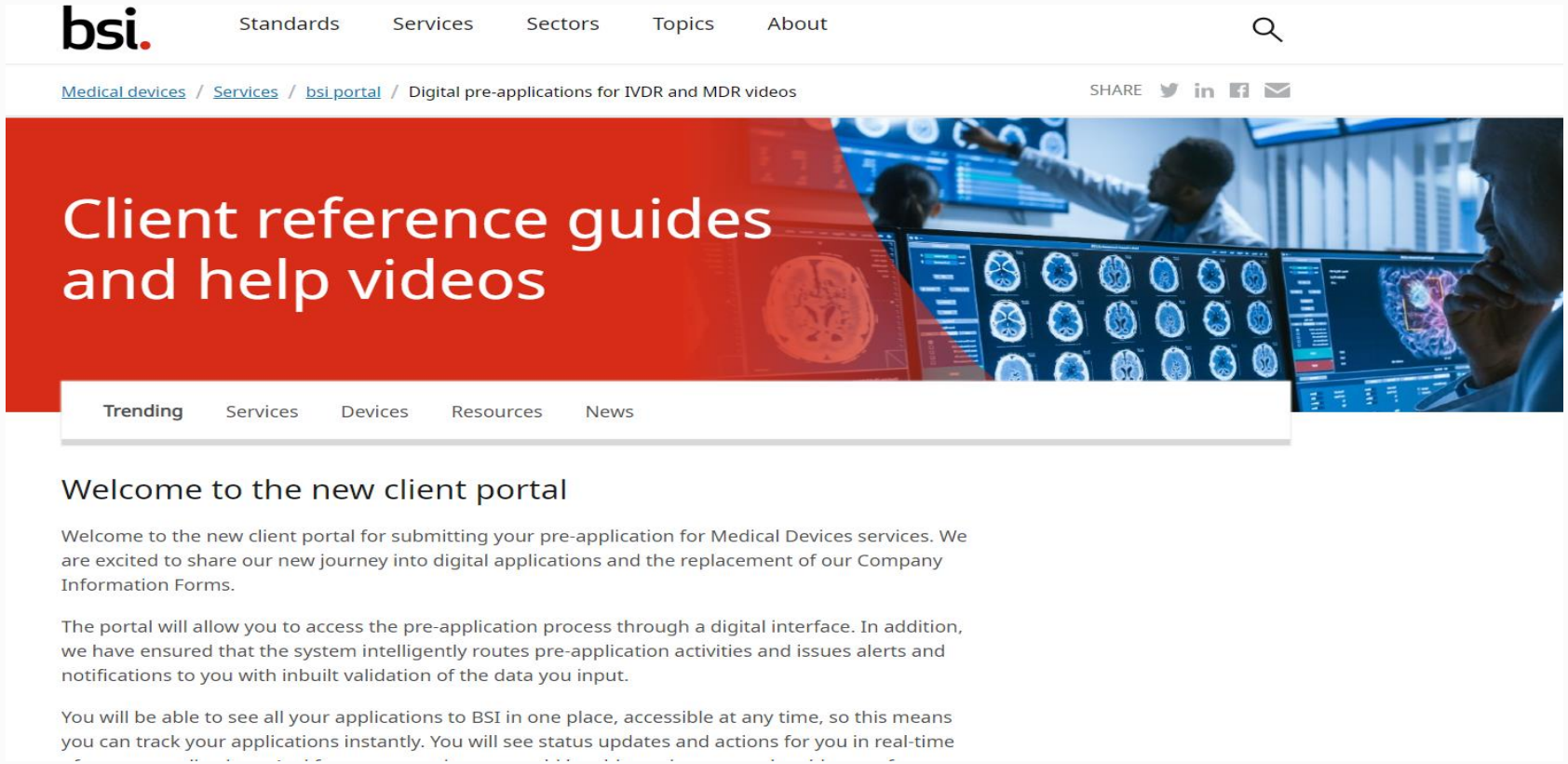


Required Data new Client:

- Certificate holder name + address
- Full Time Employee Number
- Main contact incl. phone number and email address
- Which service is requested?
- Portfolio overview

Poll Question

Digital Pre-Applications (DPA) for MDR & IVDR



DPA

Application ID - BSI 0001180900

Application Details

BSI 0001180900 - read only view

Application Submission Date

-

Services Requested - Application Type

-

MANAGE APPLICATION USERS

Status & Section(s) Completed

Status

- Application In Draft

Sections Completed

••• Select Services
Company Information
Add Devices
QMS Information
Add Sites
Supporting Documents
Other Information
Declaration
Submit

Next Step by BSI & Your Next Action

Next Step by BSI

-

Your Next Action

START YOUR APPLICATION

Resources and guidance

- BSI Medical Devices Website
- CE Marking Certification
- Medical Devices Resources
- MDR, IVDR CE Application Checklist
- CE Marking, UKCA Technical Documentation Review Services
- Client Reference Guides and Help Videos
- View Release Notes
- UDI-DI Guidance

Need Assistance?

Before requesting assistance from BSI please check the content in the 'Resources and guidance' section on the left. If this does not solve your query then use the 'Raise New Application Query' button immediately below to seek assistance from BSI

RAISE NEW APPLICATION QUERY FOR BSI 0001180900

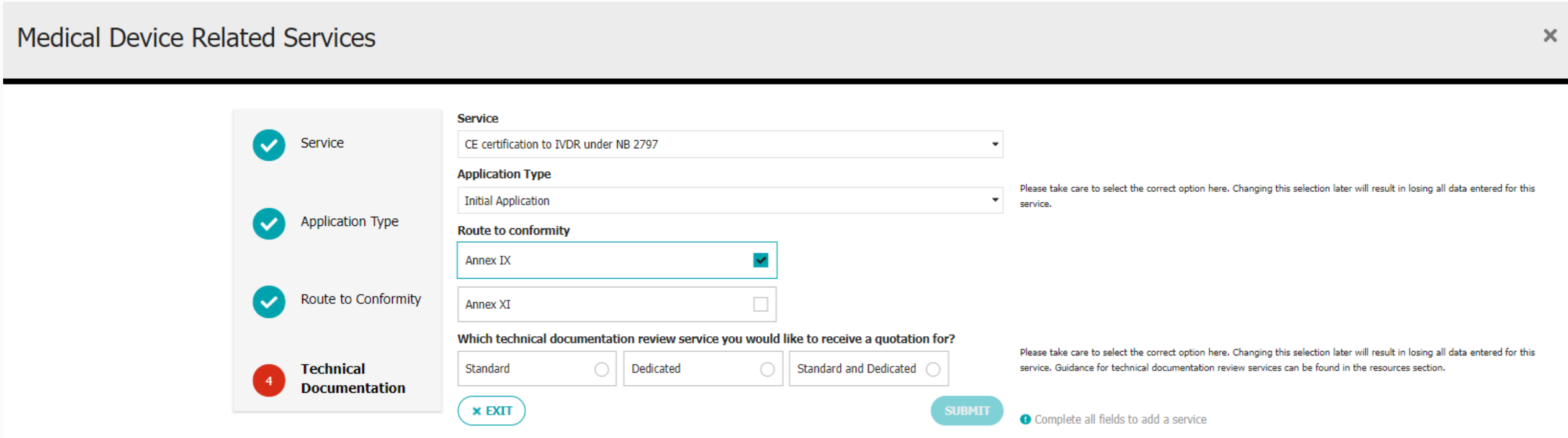
VIEW OPEN APPLICATION QUERIES

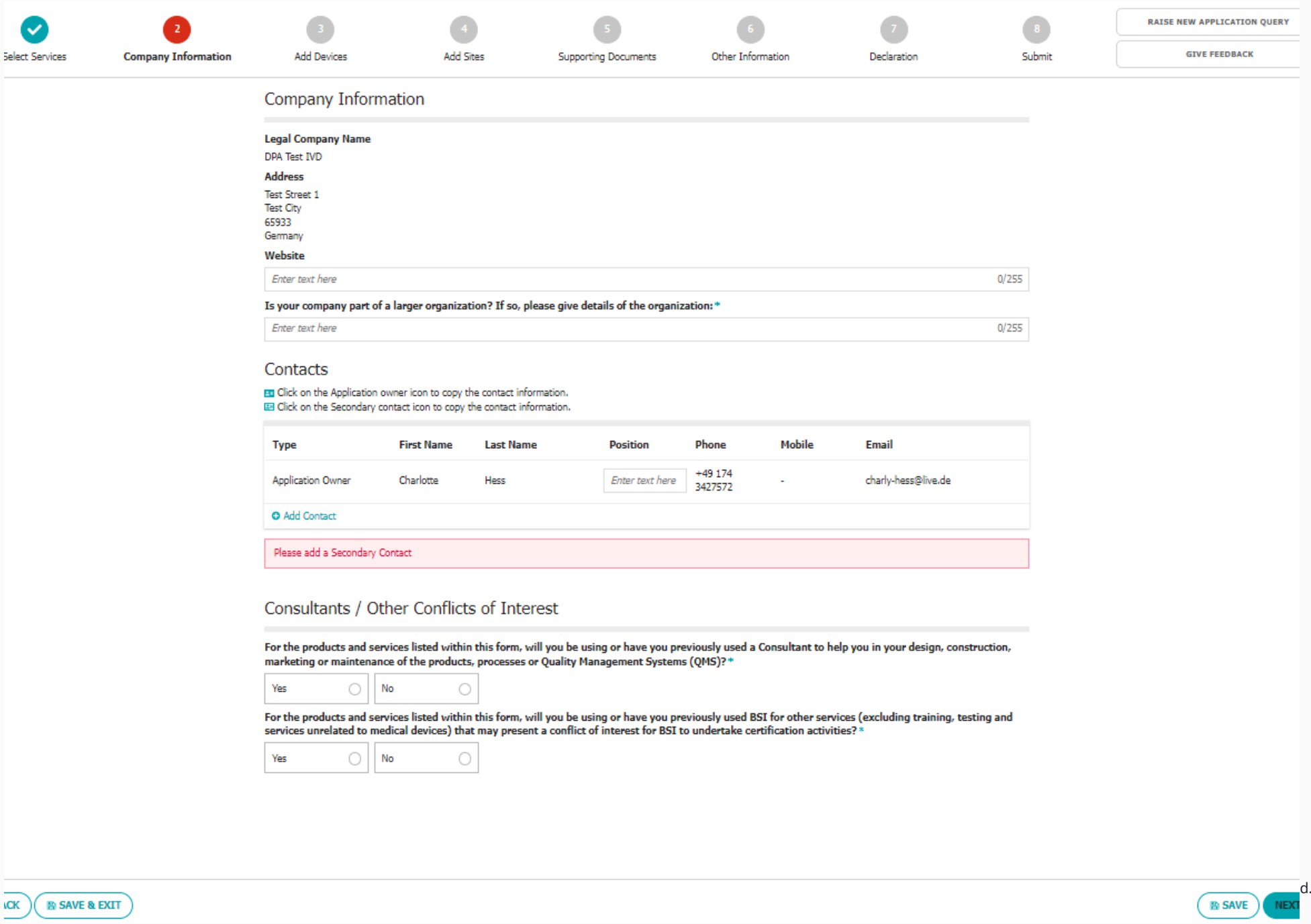
My Account

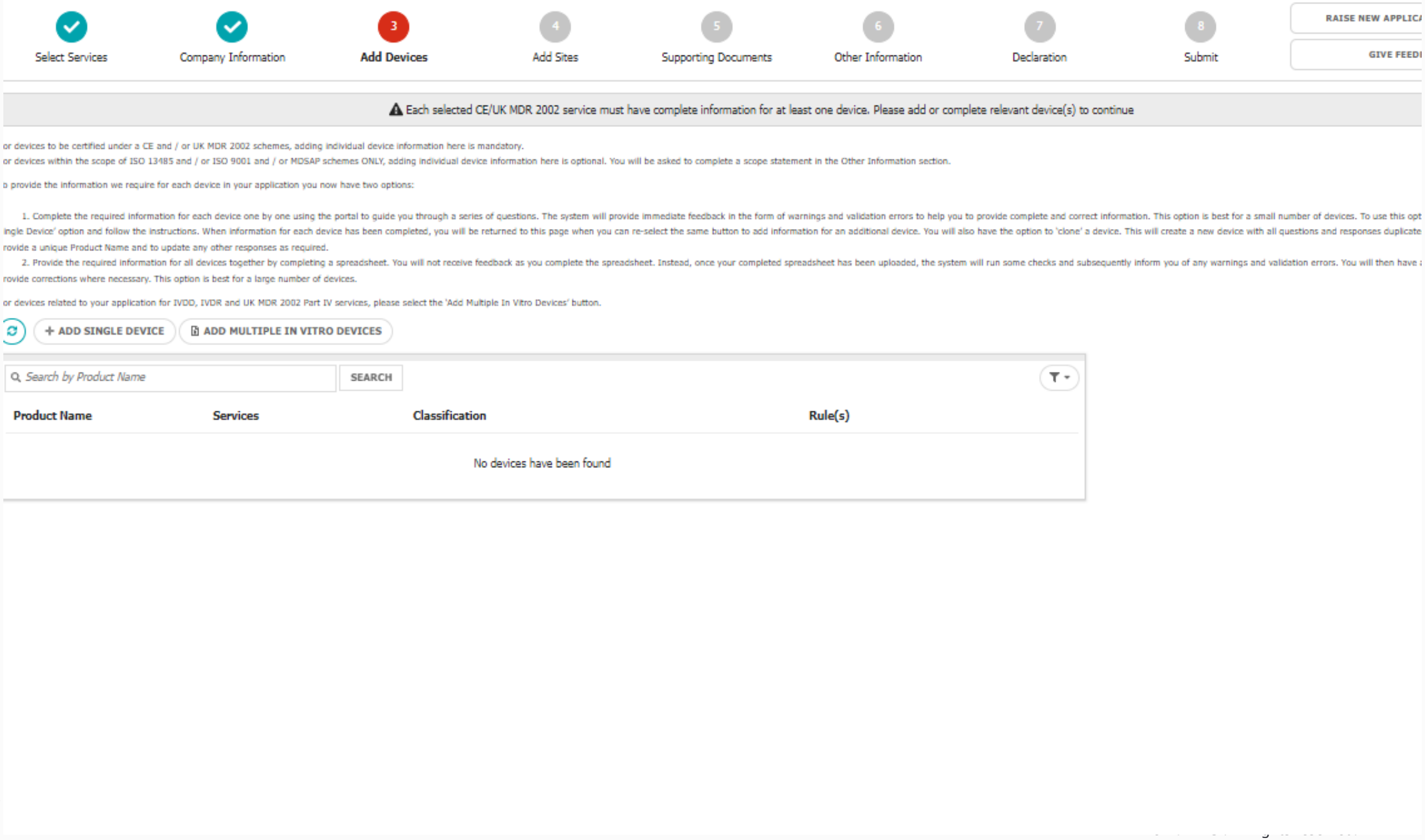
UPDATE APPLICATION OWNER

UPDATE COMPANY INFORMATION

CANCEL APPLICATION




Select Services
2
Company Information
3
Add Devices
4
Add Sites
5
Supporting Documents
6
Other Information
7
Declaration
8
Submit
RAISE NEW APPLICATION QUERY
GIVE FEEDBACK
Company Information
Legal Company Name
DPA Test IVD
Address
Test Street 1
Test City
65933
Germany
Website
Enter text here
0/255
Is your company part of a larger organization? If so, please give details of the organization:*
Enter text here
0/255
Contacts
Click on the Application owner icon to copy the contact information.
Click on the Secondary contact icon to copy the contact information.
Type
First Name
Last Name
Position
Phone
Mobile
Email
Application Owner
Charlotte
Hess
Enter text here
+49 174 3427572
-
charly-hess@live.de
Add Contact
Please add a Secondary Contact
Consultants / Other Conflicts of Interest
For the products and services listed within this form, will you be using or have you previously used a Consultant to help you in your design, construction, marketing or maintenance of the products, processes or Quality Management Systems (QMS)?*
Yes
No
For the products and services listed within this form, will you be using or have you previously used BSI for other services (excluding training, testing and services unrelated to medical devices) that may present a conflict of interest for BSI to undertake certification activities?*
Yes
No
ACK
SAVE & EXIT
SAVE
NEXT
d.


Select Services
Company Information
3
Add Devices
4
Add Sites
5
Supporting Documents
6
Other Information
7
Declaration
8
Submit
RAISE NEW APPLIC
GIVE FEEDI
Each selected CE/UK MDR 2002 service must have complete information for at least one device. Please add or complete relevant device(s) to continue
or devices to be certified under a CE and / or UK MDR 2002 schemes, adding individual device information here is mandatory.
or devices within the scope of ISO 13485 and / or ISO 9001 and / or MDSAP schemes ONLY, adding individual device information here is optional. You will be asked to complete a scope statement in the Other Information section.
o provide the information we require for each device in your application you now have two options:
1. Complete the required information for each device one by one using the portal to guide you through a series of questions. The system will provide immediate feedback in the form of warnings and validation errors to help you to provide complete and correct information. This option is best for a small number of devices. To use this opt
ingle Device' option and follow the instructions. When information for each device has been completed, you will be returned to this page when you can re-select the same button to add information for an additional device. You will also have the option to 'clone' a device. This will create a new device with all questions and responses duplicate
rovide a unique Product Name and to update any other responses as required.
2. Provide the required information for all devices together by completing a spreadsheet. You will not receive feedback as you complete the spreadsheet. Instead, once your completed spreadsheet has been uploaded, the system will run some checks and subsequently inform you of any warnings and validation errors. You will then have
rovide corrections where necessary. This option is best for a large number of devices.
or devices related to your application for IVDD, IVDR and UK MDR 2002 Part IV services, please select the 'Add Multiple In Vitro Devices' button.
+ ADD SINGLE DEVICE
ADD MULTIPLE IN VITRO DEVICES
Search by Product Name
SEARCH
Product Name
Services
Classification
Rule(s)
No devices have been found

Device Information: IVDR

1. **Device Details**
2. Classification
3. Novelty / Materials / Technologies
4. Sterilisation
5. Other Device Attributes
6. Technical Documentation

Device Details

Certificate Number(s)

Enter all relevant CE/UK MDR 2002 certificates here 0/255

Add certificate number(s) if the device is already certified by BSI under CE/UK MDR 2002.

Device Nomenclature Code

Enter Device Nomenclature Code here 0/255

Basic UDI-DI *

Enter basic UDI-DI here 0/255

UDI-DI guidance can be found here
- https://ec.europa.eu/health/medical-devices-topics-interest/unique-device-identifier-udi_en/
per https://ec.europa.eu/docsroom/documents/33623/attachments/1/translations/en/renditions/native

Part Number *

Enter Part Number here 0/255

Product Name *

Enter Product Name here 0/255

List manufacturer product name (brand name).

Intended use *

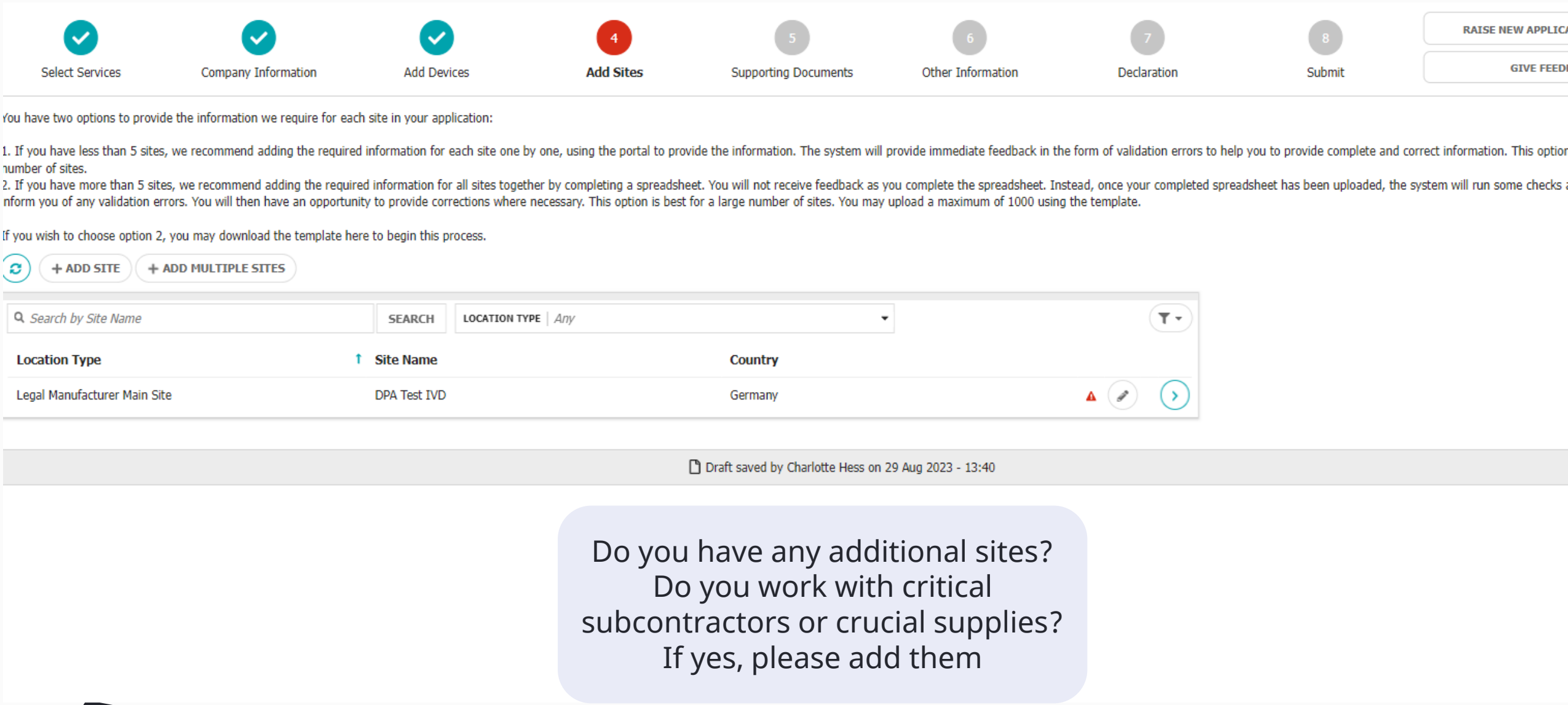
Enter the intended use here

Please make sure your intended purpose matches the requirements of Annex I 20.4.1 c

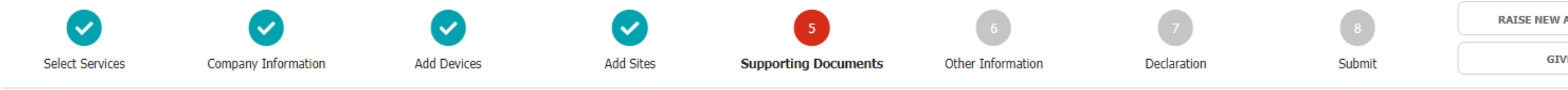
CANCEL

SAVE DRAFT

NE



Do you have any additional sites?
Do you work with critical subcontractors or crucial supplies?
If yes, please add them



Certificates

UPLOAD CERTIFICATE

Document Name	Certificate Holder	Certificate Number	Type of Certificate	Issuer	Expiry Date	Status	Uploaded By	Date Uploaded
No certificates have been uploaded to this application								

Other Documents

UPLOAD OTHER DOCUMENT

Document Name	File Type	Uploaded By	Date Uploaded
No other documents have been uploaded to this application			

If applicable add your existing certificates and latest audit report including information on NCs and CAPs

Client Readiness

When will your QMS be ready for assessment? *

dd/mm/yyyy

QMS Audit Language Requirements

Are the QMS policies and procedures written in English? *

Yes | No

Are the records (outputs from the QMS) in English? *

Yes | No

Are the auditees proficient in English? *

Yes | No

Additional Information

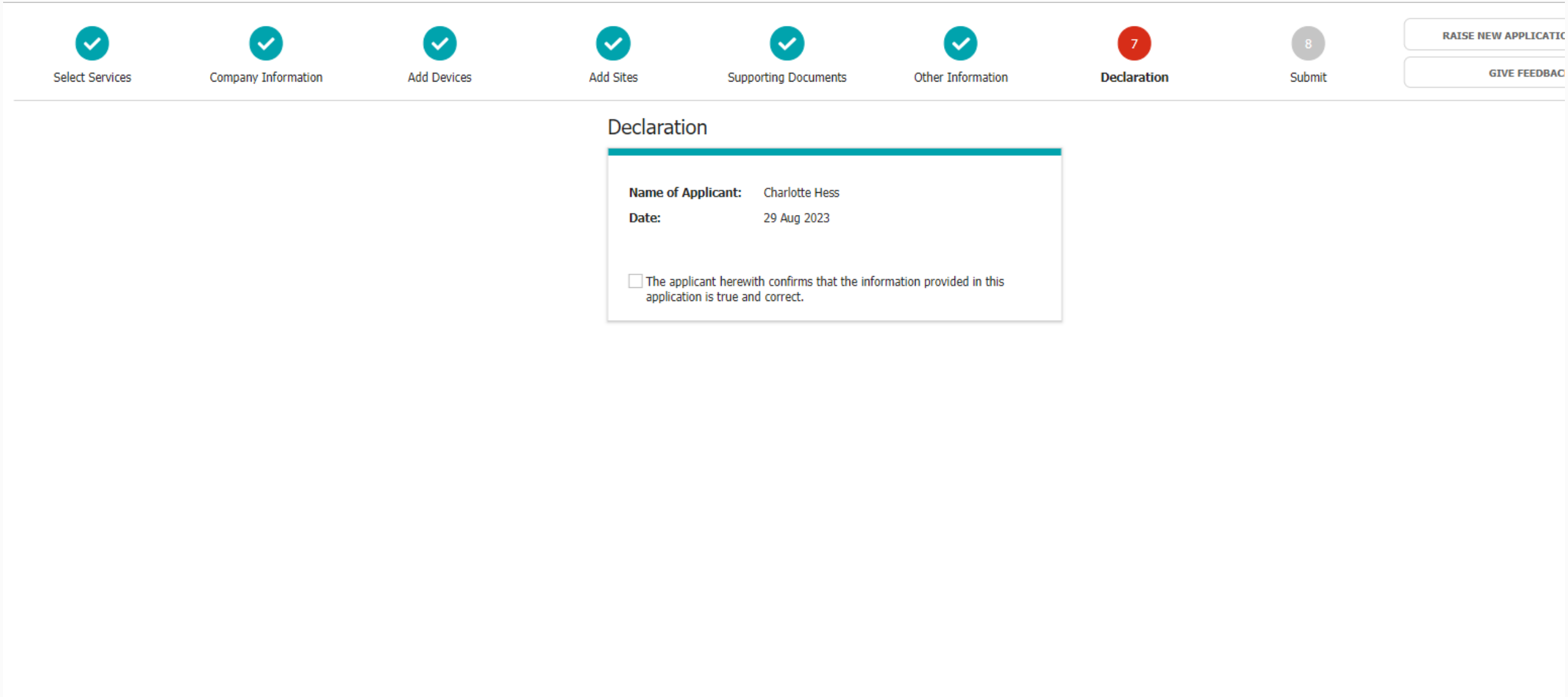
Does your facility have internet bandwidth to support video/audio and document sharing? *

Yes | No

Are there any areas within the facility that have restricted internet bandwidth? *

Yes | No

If applicable, and/or to your knowledge, does your critical subcontractor's facility have the internet bandwidth to support video/audio and document sharing? *



Selection Summary

When you accept and return your signed contract(s) you will be required to upload each of the documents listed in the MDR / IVDR application checklist. A copy of this checklist can be found in the resources section.

Service(s) Selected

CE certification to IVDR under NB 2797

Site(s) Added

1

Device(s) Added

1

IVDR Contract Available – Next Steps

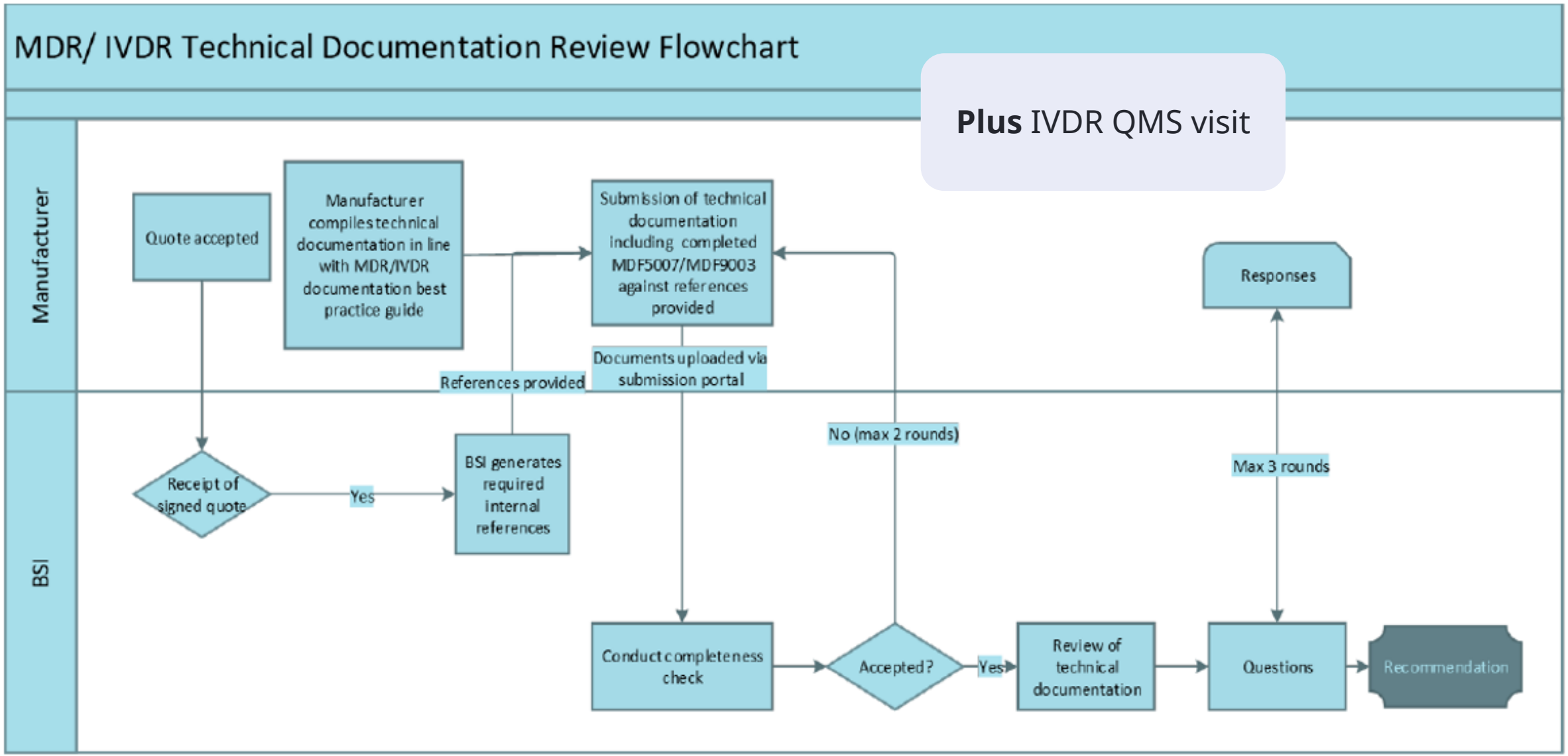
- For contract Review, the signed contract and all documents listed in the CE application Checklist are needed
    - Draft version will be accepted, however IVDR compliance is key
- Following a positive outcome of contract review, the certification process can start

MDR, IVDR CE application Checklist

Instructions for Manufacturers: Please complete the table below with the corresponding document references for the items specified and provide copies of the actual documents as attachments along with the signed BSI contract

Document Type	Document References
Sample draft Declaration of Conformity (as per Annex IV of MDR/IVDR) for the highest classification device included in the application	
Quality Policy	
Quality Objectives	
Quality Manual	
PMS Procedure	
Sample PMS plan for the highest classification device (or groups of devices) included in the application	
Vigilance reporting procedures covering incident reporting, field actions, periodic summary reporting, and trend reporting	
A description of the procedures in place for keeping PMS plans, PMCF plans and vigilance procedures up to date	
Specific to MDR applications	
Sample clinical evaluation plan for the highest classification device (or groups of devices) included in the application	
A description of procedures in place for keeping the clinical evaluation plans up to date taking into account the state of the art	
Sample Post Market Clinical Follow-up (PMCF) plan for the highest classification device (or groups of devices) included in the application	
Specific to IVDR Applications	
Sample performance evaluation plan for the highest classification device (or groups of devices) included in the application	
Procedures for keeping the performance evaluation plans up to date taking into account the state of the art	
Sample Post Market Performance Follow-up (PMPF) plan for the highest classification device (or groups of devices) included in the application	
Note: For self-testing, near-patient testing devices that are class B, class C or class D, if practicable and required, BSI may request an example of the device during the conformity assessment process.	

BSI MDR/IVDR process



Plus IVDR QMS visit

BSI Technical Documentation Review Process

Review stage	Completeness Check	Review Round 1	Review Round 2	Review Round 3	Review Closure
Specifics	Maximum 2 rounds of checks until complete file is provided	Longest period of NB review. Questions issued covering all identified deficiencies	NB reviews responses to R1 deficiencies. May have more questions	NB reviews responses and issues final set of questions	NB reviews final responses. Large gaps lead to Refusal

Review will not start unless all studies are complete

Take calls offered by your technical expert!

Listen to Webinars on PE expectations

Technical Documentation - Requirements

Searchable, book-marked PDF

NB experts cannot draw conclusions from ambiguous documentation

A complete and well-organized file decreases NB review time and your costs.

Use justifications for non-applicability

IVDR Terminology

Poll Question

BSI IVD – Available Resources

Compliance Navigator

Compliance Navigator

The digital revolution in regulatory document management.

Manage your risk effectively and save time with this all-digital platform. Backed by BSI's expertise as a leading standards publisher, you can rest assured you'll be in safe hands.

Find out more >

Training

Training courses

We offer training tailored to the In Vitro Diagnostic Regulation to help support and grow your business.

IVDD to IVDR Transition →
Requirements of the IVDR for CE Marking →
Implementation of the IVDR for CE Marking →
Requirements and Implementation of the IVDR →
Technical documentation for the IVDR →
Performance evaluation and clinical evidence for IVDs →

View all training

BSI IVD – Available Resources

In Vitro Diagnostics Regulation | BSI Medical Devices

Brochures

IVDR conformity assessment routes

Our guiding brochure will support you in understanding conformity assessment routes and in selecting the most suitable for your in-vitro diagnostic device.

Download the brochure →

Webinars

Resources

IVDR documentation submission

Download our IVDR best practices guidelines to help you prepare and structure your Technical Documentation when planning your IVDR conformity assessment application to BSI.

Download the document →

If you'd like to know more about one of our products or services, please click on the link below to fill out the form and a member of our team will be in touch.
https://www.bsigroup.com/en-GB/forms/request-a-quote-medical-devices/

Questions

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