

# Transition to the IVD Regulation - MedTech Europe Survey Results for October 2022

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## Executive summary

It is undisputable that the amending Regulation (EU) 2022/112<sup>1</sup> of the IVD Regulation's transitional provisions adopted in January **brought significant relief and restored production and availability of IVDs to patients, laboratories and healthcare systems**. It also supported **the transition to the IVDR**: around 21% of today's total IVD market are already certified under the IVDR. This represents a **three-fold increase relative to July 2021**.

At the same time, this survey demonstrates that certification bottlenecks leading up to May 2025 are still possible: 51% of Class D legacy devices belong to manufacturers **which still do not have an agreement with a Notified Body** and cannot yet be certified under IVDR unless such an agreement is secured; a disproportional number of **small and medium enterprises (SMEs) still do not have an agreement with a Notified Body** designated under the IVDR, which may result in 54% of SMEs not being able to certify their tests unless agreements are concluded on time.

To support the transition to the IVD Regulation including for legacy and innovative IVDs, **attention should be given to further building up the infrastructure of the regulatory system, and making conformity assessment shorter, more efficient and more predictable**. This includes (but is not limited to), speeding up designation of Notified Bodies and ensuring a workable EU Reference Laboratory system, as well as tackling inefficiencies at every stage of the certification system.

Finally, great attention is given to innovation: the survey shows a **28% drop in manufacturers who would prioritise the EU for first product launches**.

## Survey results in a nutshell

- **~91% of companies benefitted from the January 2022 amendment providing extended transitional periods.**
- **IVD manufacturers are in transition to the IVD Regulation.** Out of total IVDR expected devices (26.597), 34% already are CE marked. ~94% of large companies and 47% of SMEs have an agreement in place with at least one Notified Body, indicating that they have started the process to transition to IVD Regulation.
- **Certification bottlenecks are still possible leading up to May 2025.** 51% of Class D legacy devices belong to manufacturers who do not have an agreement in place with a Notified Body.
- **Access to a Notified Body has improved since July 2021 but remains a significant issue especially for SMEs.** 53% of SMEs and 6% of large companies *do not have an agreement* with a Notified Body designated under the IVDR.
- **17% of today's devices will be discontinued – in most cases due to the cost of CE-marking under IVD Regulation**
- **The length of each stage of conformity assessment varies hugely. Efficiencies can be gained in reducing time-to-certification and increasing predictability of the system at every stage of conformity assessment.**
- **IVD Regulation will impact early access to innovative medical tests in Europe.** There is a 28% drop in manufacturers who would prioritise the EU for first product launches.

## Introduction

This is the second year MedTech Europe has run a survey of the IVD sector about the state of the transition to the IVD Regulation. A visual representation of the findings in 'slide deck form' may be found in the Annex under [this link](#).

The 2021 survey<sup>2</sup> was run before amending Regulation (EU) 2022/112 was published, putting in place extended transitional periods which allow most IVDs to remain on the market in conformity with the IVD Directive (amongst other conditions<sup>i</sup>). The 2022 data comes nine months after the amending Regulation and

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<sup>i</sup> legacy devices must have had their EC declaration of conformity drawn up before the 26 May 2022, they can have no significant changes to their design and intended purpose and they must already comply with certain requirements of the IVD Regulation to stay under the extended transitional periods. IVD Regulation requirements applicable to legacy products are in the areas of registration of actors and devices, post-market surveillance and vigilance and market surveillance;

five months after the date of application for the IVD Regulation, meaning that the survey has been run in an extraordinary year which has seen all stakeholders in the IVD sector adjust to considerable change in the regulatory system.

During the period from January to October 2022, a number of elements which are important to the certification system became available:

- The number of Notified Bodies grew from six to seven; this represented less than half of all Notified Body applications for designation under IVDR
- For companion diagnostics, the pathway to include European Medicines Agency in the conformity assessment became operational
- Common specifications for class D devices were published, covering several device types. Those devices no longer need to go through the expert panel review if they are the first of their type. 16 Performance Evaluation Consultation Procedure (PECPs) were issued<sup>3</sup> by the IVD Expert Panel
- A solid array of MDCG guidance was published for IVD legacy devices; this is relevant for supporting appropriate management of the extended transitional periods

At the time of writing, important elements are still to be made available, including additional Notified Bodies, EU Reference Laboratories, guidance on performance studies and the European medical devices database (EUDAMED), amongst others.

This report on the results of the 2022 survey assesses the state of the sector in transitioning to the IVD Regulation. It points to where the resources of the regulatory system may best be focussed and efficiencies in the system could be gained. Lack of access to a Notified Body together with the cost and complexity of the system, are reported as serious barriers for SMEs to engage in conformity assessment. The work needed to certify devices under IVDR remains considerable and it is possible for blocks or bottlenecks in certification to appear ahead of the first transitional period deadline of May 2025. The system could see much improvement in becoming more efficient and predictable; in particular, conformity assessment can be complex, and timelines can vary wildly between submission of an application and receipt of a Notified Body certificate. Important here will be full implementation of the 19 actions under MDCG 2022-14<sup>4</sup> (amongst other solutions) and ensuring that all class D devices can smoothly transition with or without EU Reference Laboratories.

One expected impact of the IVDR will be to make Europe less attractive for innovative devices. IVDR is reported by many respondents as providing resource and cost challenges which may impact those devices whose revenue is not expected to cover the cost of acquiring and maintaining CE-marking under IVDR. The European Commission intends soon to conduct a root cause analysis of structural issues in the IVD Regulation and Medical Devices Regulation including identifying where there are blocks to innovation, which will be important to ensuring European patients gain early access to innovative diagnostics.

As ever, industry stands by ready to support the full and proper implementation of this regulation.

## Survey methodology

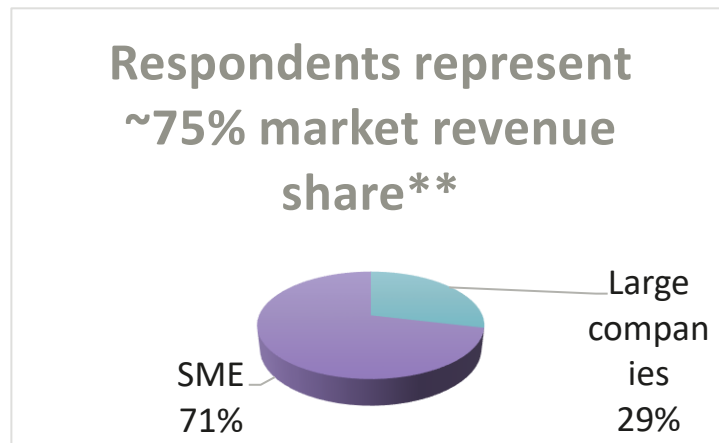
### Abbreviations

|          |  |
|----------|--|
| MDCG:    | Medical Devices Coordination Group         |
| EUDAMED: | European Medical Devices Database          |
| IVD:     | <i>In vitro</i> diagnostics medical device |
| IVDR:    | IVD Regulation (EU) 2017/746               |
| IVDD:    | IVD Directive (EC) 98/79                   |
| NB:      | Notified Body                              |
| QMS:     | Quality management system                  |
| TDA:     | Technical documentation assessment         |
| SME:     | Small and medium sized enterprises         |

The links to various publications and sources can be found at the end of this report.

The survey was run by MedTech Europe to assess the state of the *in vitro* diagnostics medical device (IVD) market transition to the IVD Regulation. Approximately 40 survey questions were posed. Some of the questions for this survey were created in cooperation with the Medical Devices Coordination Group (MDCG).

Between 30 September and 27 October 2022, the survey was sent to all IVD manufacturers members of MedTech Europe. We warmly acknowledge National Associations and AdvaMedDx<sup>i</sup> for encouraging their own member manufacturers to participate. Only one submission per manufacturer was allowed. The numerical results have been aggregated.



110 manufacturers participated in the survey<sup>ii</sup>. This represents an estimated market revenue coverage of 75%<sup>5</sup>. Most respondents (77) were small and medium-sized enterprises (SME), with 33 responses from large

<sup>i</sup> AdvaMedDx, a division of the Advanced Medical Technology Association (AdvaMed), represents over 70 manufacturers of innovative *in vitro* diagnostic (IVD) medical device tests in the U.S. and abroad. AdvaMedDx seeks to advance policy to promote innovation and expand access to quality testing;

<sup>ii</sup> compared to 115 responses (90% of market share) in the IVDR market readiness [survey](#) coordinated by MedTech Europe in 2021;

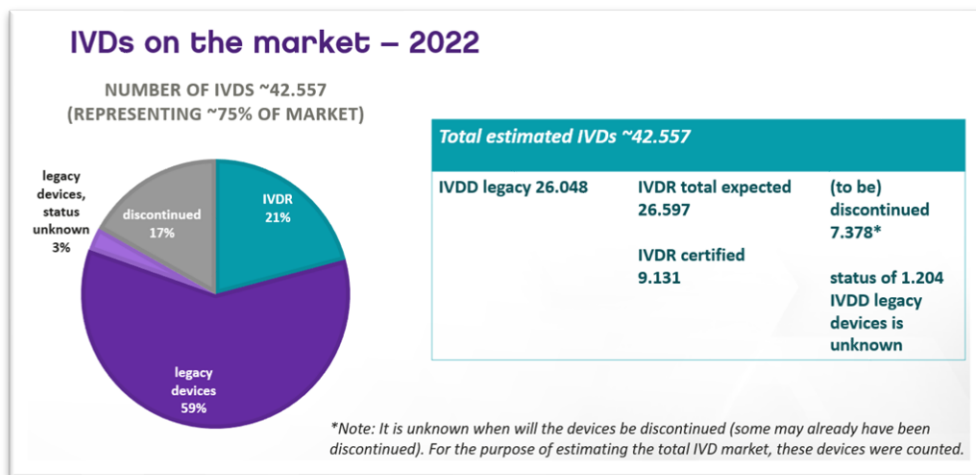
manufacturers. When comparing these results with the participation last year: in 2021, 115 manufacturers responded, covering an estimated 90% of the market share (SMEs: 82, large manufacturers: 33).

The below provides an analysis of the 2022 survey data. Where appropriate, comparison has been made to the 2021 survey data and to the European Commission survey<sup>4</sup> of Notified Bodies on applications and certifications.

## Results

### Overall IVD market in transition to IVDR

The IVD sector is making progress in managing the transition to the IVDR, as 34% of devices already have CE marking under IVDR. Therefore, work must continue to certify the remaining 66% of devices expected under the IVD Regulation.



Around 21% of today's total IVD market (or 34% of IVDs which are expected to become CE-marked under the IVDR (CE IVDR)) are already CE IVDR. This represents a **3-fold increase relative to July 2021**, when just 7% of devices were CE IVDR. On this regard, 91% of the 2022 survey respondents stated that they were helped to some degree by the amending Regulation (EU) 2022/112, which put in place extended transitional periods for most devices compliant with the IVD Directive and certain IVDR requirements<sup>i</sup>.

The total IVD market represented by the survey respondents is ~42,557 devices, of which over 26 thousand are expected to become CE IVDR. It is important to note that the survey respondents represent a roughly 75% share of the EU market revenue, meaning that all figures given in this analysis must be interpreted in that regard. Respondents indicated that they would discontinue just over seven thousand devices; as the survey did not ask when these devices would be discontinued, this category is counted in the total of today's IVD market.

<sup>i</sup> to remain under the extended transitional periods, legacy devices can have no significant changes to their design and intended purpose and they must comply with IVD Regulation requirements relating to registration of actors and devices, post-market surveillance and vigilance and market surveillance;

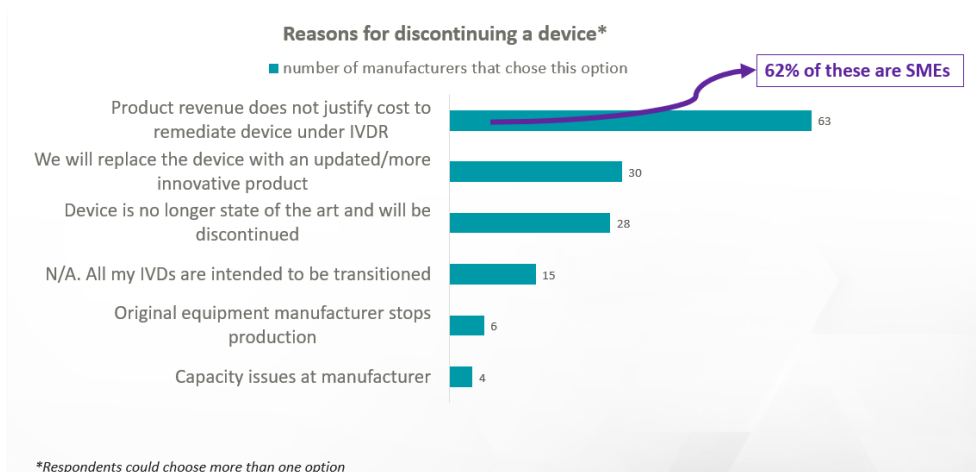
Notified Bodies have a large amount of work to get through with current clients, who have not yet submitted applications for all their devices. Work must continue to certify 66% of devices expected under the IVD Regulation. Of the total number of IVDD legacy devices, 74% are with a manufacturer that has an agreement with at least one Notified Body, but 26% are not covered by any Notified Body agreement. In particular SMEs (and a few larger companies) need to sign on with a Notified Body before they may start conformity assessment under IVDR. The number of legacy devices not yet covered by a Notified Body may be much higher in reality (although the total number of IVD manufacturers in Europe is not known, it is expected that there are many SMEs which have not participated in this survey).

### Discontinuation of devices

**7.378 devices – or 17% of today’s IVD total market – will be discontinued by the respondents.**

The 2021 survey reported 22% loss in devices, which is comparable to the 17% reported in 2022 (considering the different market revenue shares covered, ~90% in 2021 and ~75% in 2022). When the market revenue share represented by the respondents is considered, these findings align well to the number of devices which were expected to be discontinued in the 2021 MedTech Europe survey. Roughly half or 3.869 devices will be discontinued by large manufacturers and 3.509 by SMEs. The survey did not investigate *which* devices will be discontinued; therefore, it is unknown if these are unique or niche devices or part of a product group.

It is assumed that some of the devices have already been discontinued, but it is possible that some manufacturers may decide to keep devices on the market until the end of the relevant transitional period if they plan to discontinue them due mainly to the cost of remediating them under the IVDR.



The main reason given for discontinuation is ‘Product revenue does not justify cost to remediate device under IVDR’. 62% of respondents choosing this option are SMEs, which indicates that discontinuation decisions taken by many SMEs largely are based on the expectation that the IVDR remediation cost will outweigh the product revenue. This first option could be confounded by lack of transparency over conformity assessment

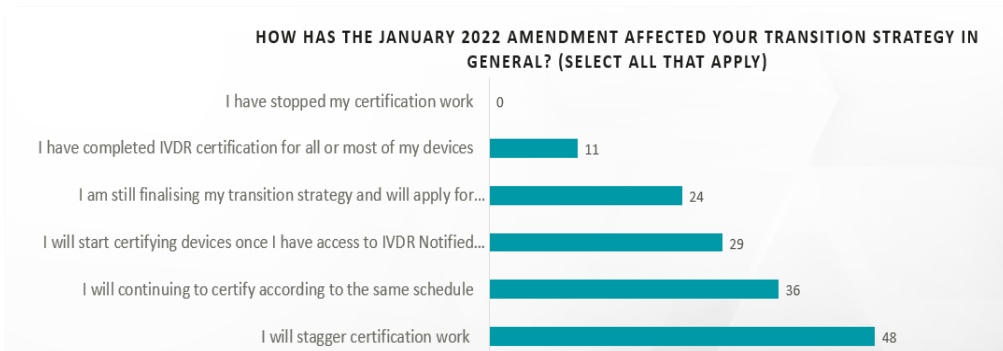
and post-market costs, limited resources and lack of predictable pathway – in other words a lack of ability to plan. Therefore, this point might hit SMEs particularly hard.

The second and third options chosen are both part of device lifecycle management. 30 respondents indicated that they would replace the device(s) with an updated or more innovative product (the number of devices which would be replaced in this way is unknown). 28 respondents indicated that they would discontinue the device(s) because it is no longer state of the art.

Only 15 respondents indicated that they would transition all their devices without discontinuation, which means that 95 respondents will discontinue one or more of their devices.

### How is the industry approaching the transition to the IVDR?

94% of large companies and 47% of SMEs have an agreement in place with at least one Notified Body, indicating that they have started the process to transition to IVDR. Establishing an agreement with a Notified Body under IVDR is a meaningful first step, especially considering that it may be a novel process for many companies (under the IVD Directive, only 8% of devices required certification and therefore an agreement with a Notified Body to be in place).



No respondents indicated that they were stopping their certification work, and only 11 indicated that they had completed all or most of their IVDR certification work already. This means that most respondents are in transition to the IVDR for their devices. Of those respondents, most reported they will stagger their certification work in some way according to the extended transitional periods. Fewer but still many respondents are continuing to certify their devices according to the same schedule they were on before extended transitional periods were made available under amending Regulation (EU) 2022/112.

Given that just over half of SMEs still do not have an agreement in place with a Notified Body, it is not surprising that the third most popular choice was to indicate that the respondent would wait for access to a Notified Body before starting certification work.

The extended transitional periods are staggered according to risk class, starting with the highest risk class. It seems reasonable to assume that this progressive roll out of the IVDR – and the ability to stagger certification work as an option – has likely prevented a certification bottleneck from appearing in 2022 and



should prevent one in 2023. At the same time, the amount of certification work to be completed by the end of each of the new transitional periods should not be underestimated and challenges in the system infrastructure remain.

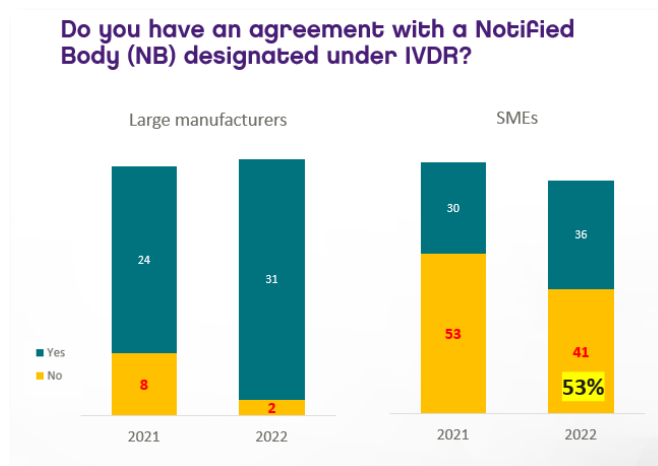
Industry is not always in the driving seat for deciding if or how certification work will be staggered. Extension of IVDD certificates during the 1<sup>st</sup> half of 2022 was a priority for Notified Bodies and those clients with IVDD certificates, which contributed to a delay in Notified Body work on many IVDR applications. Notified Bodies started conformity assessment for class D relatively recently; by contrast the certification work for class B and C has been proceeding steadily (although many respondents reported challenges including delay in the conformity assessment process leading up to certification).

It might be expected that some Notified Bodies may prioritise the work which must be completed in the next phase of the transitional periods, e.g., class D certifications. Some Notified Body capacity may also be impacted by any certification bottlenecks for the Medical Devices Regulation (EU) 2017/745. Should this be the case, it will have some effect in staggering other certification work unless the Notified Body has capacity to take on all work simultaneously. At the time of writing the European Commission has proposed extended transitional periods for medical devices, which if published into law would overlap with transitional periods for IVDs and could pose resource challenges for the administrative staff of Notified Bodies who are designated under both the Medical Devices Regulation and IVD Regulation.

### Access to a Notified Body

**Access to Notified Body has improved since July 2021 but remains a significant issue.**

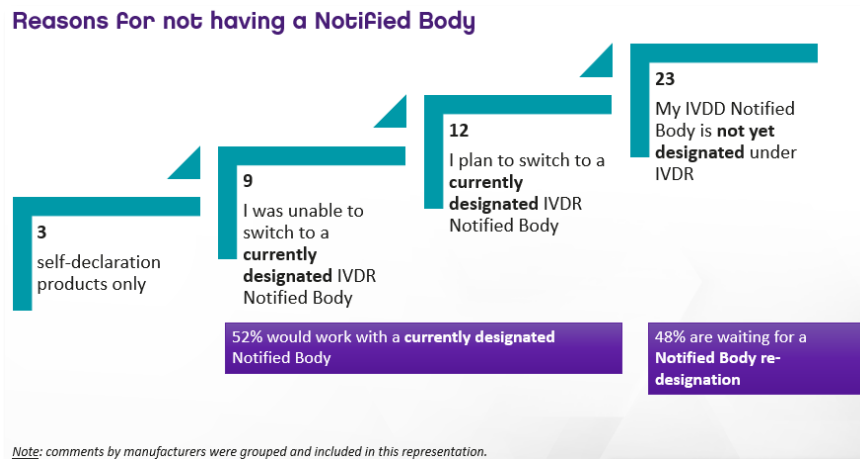
Overall, more manufacturers have signed a contract with at least one Notified Body compared to the situation in July 2021. However, the situation should be considered as worrying in particular for the SME segment of the market. For those companies which indicated that they had a contract with at least one Notified Body, it should be noted that such agreement may or may not cover the whole device portfolio of that manufacturer.



94% of large companies and 47% of SMEs have a contract in place, which is a marked improvement over July 2021, when only 75% of large companies and 36% of SMEs had a contract.

53% of SMEs did not yet have a contract with a Notified Body in October 2022, which is a decrease since July 2021, when 64% of SME respondents indicated they had no contract. While this decrease is an improvement, it still indicates that over half of SMEs still do not have access to a Notified Body. This is a significant challenge for the whole market. It can be considered that within the SME segment of the market there could be unique assays and software which address unique clinical needs.

Signing the contract is an important step before the conformity assessment process and can easily take 3-6 months or even longer if the Notified Bodies being contacted are less responsive. Also, establishing the relationship takes time and there will be fundamental questions to address such as whether the manufacturer has an ISO 13485 certificate with the Notified Body, can the device portfolio be covered in the scope of the Notified Body resources, explaining how to work together, etc.



48% of SME respondents said that the reason they did not have access to a Notified Body is that they have not yet been designated. This indicates that regulators would considerably support this part of the SME market if they could speed up the process of designating Notified Bodies which meet the IVDR requirements. It should not be considered as straightforward to switch to a new Notified Body. This triggers a new ISO 13485 certification procedure with the new Notified Body before IVDR conformity assessment can even start. A new Notified Body will also have different procedural, documentation or even requirement expectations which can take time and experience to become accustomed to.

Although only 9 respondents claimed that they were unable to switch to a currently designated Notified Body, comments for this section indicated that many respondents had challenges in securing a Notified Body agreement, e.g., due to lack of response on the part of the contacted Notified Bodies, lack of their own resources or of Notified Body resources to dedicate to signing on new clients, Notified Body fees, etc.

As stated above, 74% of legacy IVDs are with a manufacturer who has an agreement with at least one Notified Body. This means that 24% of legacy devices (or 6.694 devices) are not covered by a Notified Body agreement.

Innovation and significant changes also are impacted whenever the manufacturer does not have a Notified Body agreement in place. The survey asked for the number of new and innovative devices expected in the next 12-18 months, including:

- first-launch devices (i.e., devices which have never been CE-marked before but will need CE-marking under the IVD Regulation to access the EU market)
- devices with significant changes to device design or intended purpose.

30% of these first-launch devices and 53% of devices which will undergo a significant change, are not yet covered by a Notified Body agreement. These updates to the devices can happen only if the access to a Notified Body is secured fast. Even should the manufacturer secure a Notified Body agreement (which can take 3-6 months or more), the process to certify innovative and significantly updated devices would take at least 6-12 months to complete EU QMS and where relevant, 13-18 months or more for EU TDA.

## **Workload to be completed by Notified Bodies by May 2025**

**Most legacy devices still need to be certified on time for their extended transitional period deadlines<sup>i</sup>. Certification bottlenecks still are possible leading up to May 2025 for a variety of reasons, including the considerable (and overlapping) workload required by Notified Bodies leading up to May 2025, 2026 and 2027, the lack of Notified Body agreement with over half of the SME market, and specific challenges for getting Class D devices certified.**

### **Challenge 1 leading up to May 2025 – workload**

There is considerable a workload for Notified Bodies still to be completed before May 2025. This workload will overlap with each workload for May 2026 and May 2027. The workload for May 2025 includes:

1. Notified Bodies have confirmed<sup>6</sup> they have 544 applications open for various device classes, which should be considered as minimum ongoing work, given that many more applications should be expected by May 2025. Most of these current applications are for class B and C devices.
2. 1.188 class D devices require EU QMS and EU TDA certification. Class D will be a big portion of EU TDA certificates. Until relatively recently, many Notified Bodies either did not accept applications for class D or accepted the applications but did not proceed with their conformity assessment. European Commission data from Notified Body survey provides the most complete picture of the number of IVDD certificates which will expire in 2023, 2024 and 2025 and how many devices they cover. According to this data, at least 1.551 IVD Directive certificates expire before 2025.

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<sup>i</sup> extended by the amending regulation (EU) 2022/112, current transitional provisions are:

May 26, 2025 for Class D devices  
May 26, 2026 for Class C devices  
May 26, 2027 for Class B devices  
May 26, 2027 for Class A sterile devices;

3. 1.115<sup>i</sup> devices are expected to be first-launch or significantly changed and will need CE-marking in the next 12-18 months. It is unknown how many will require only EU QMS or also EU TDA certification.
4. Conformity assessment for class C must start well in advance of May 2026, especially for self-tests, near-patient tests and companion diagnostics since these need both EU QMS and EU TDA certification.
5. Oversight activities related to devices already certified under IVDR must be undertaken. This survey did not quantify that workload; however, it should represent considerable ongoing and annual work (including surveillance assessment, review of PSUR, review of summary of safety & performance, vigilance activities, management of change notifications, and more).

### **Challenge 2 leading up to May 2025 – access to a Notified Body**

Most manufacturers which have not yet contracted with a Notified Body and started conformity assessment are SMEs. For devices to transition to IVDR on time, it will be critical for these manufacturers to sign on with a Notified Body, if possible, well in advance of the end of the relevant transitional period(s).

Respondents indicate that 51% of Class D legacy devices are not covered by a Notified Body agreement.

In theory, it should be simpler for the Notified Body to complete the certification process with the SME who has few devices, than it would be to complete the certification process with the large company who has many devices and several manufacturing sites. In practice, the SME segment of the market is expected to be a more challenging segment of the market for Notified Bodies to cover:

- The Notified Body must audit one or more manufacturing sites, review at least one technical file for sampled devices and assess each technical file for devices requiring EU TDA certification.
- 53% of the SME respondents reported that they did not have access to a Notified Body. Most are waiting for their Notified Body to be designated. Other SMEs reported various difficulties in reaching an agreement with a currently designated Notified Body. A couple of SMEs comments noted that they did not (yet) need a Notified Body or that they expected they would still be in time to finalise certification later. Taken together, the data indicates that it may not be straightforward either for the manufacturer nor the Notified Body to find each other and sign an agreement, unless they already had existing agreements in place under the IVD Directive or for the purpose of ISO 13485.
- This survey did not evaluate the cost of transitioning to the IVDR. Nonetheless, it should be noted that in their comments to various questions, SMEs often cited as barriers to transitioning to IVDR, the high investment needed for IVDR including resource and cost requirements together with a lack of predictability in scheduling conformity assessment.

### **Challenge 3 leading up to May 2025 – specific challenges for certifying all class D devices on time**

From a public health perspective, it is critical that high-risk tests remain seamlessly available to European healthcare systems, e.g., because they are needed to screen the European blood supply, check cells and organs for transplantation or manage infectious disease outbreaks such as COVID-19 (SARS-CoV-2).

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<sup>i</sup> 634 innovative devices + 491 significantly changed devices = 1.115;

Many Notified Bodies have only just started conformity assessment<sup>i</sup> for class D devices and very few certifications have been issued<sup>7</sup>. It is possible that the first EURLs may be designated by end-2023, which means that they would become a mandatory part of the conformity assessment process for certain class D devices before the end of the extended transitional period. For those devices to transition smoothly to the IVDR by May 2025, it is important that regulators ensure that newly appointed EURLs are an enabling rather than confounding factor in the conformity assessment system.

The fact that many certificates are renewed to May 2025 means that there could be a bottleneck in Notified Body workload coming in May 2025. There will be no grouping under technical documentation assessment (TDA) certificates as existed under the IVD Directive. The number of IVDD certificates and their expiry dates do not give a complete picture of the workload needed to transition class D devices to IVDR: many legacy devices do not have IVDD certificates today and will become class D in the future needing IVDR certificates by May 2025. It is relevant therefore to look at number of devices rather than certificates to understand the workload which is required. In the findings from this survey, respondents expected 1.188 class D devices<sup>ii</sup> under IVDR, which should roughly correlate to EU TDA certificates.

Given the slow pace at which certificates are issued and the unpredictability of the regulatory process, time and complexity for these high-risk devices, some manufacturers could look into alternative solutions to adjust to the market. One of the possible strategies could be taking Class D devices off the market and/or downgrading to Class C by limiting the scope (intended purpose) of these devices.

One approach which could help is for Notified Bodies to leverage evidence from part of the IVD Directive file (MDCG 2022-14, Action 2) and thereby speed up the conformity assessment process. It will be important to have clarity as soon as possible, on which evidence can be used from the IVD Directive file for this purpose.

To transition all devices on time, there is considerable work for Notified Bodies which should not be underestimated. Manufacturers need to have everything in place and apply well in advance of the end of the transitional periods (and have their application accepted) in order to give themselves the best chance of timely certification. Potential blocking factors continue to be lack of access to a Notified Body especially for the larger part of the SME market and the unknown role which EU Reference Laboratories will play once they become available. The certification process is just starting for most class D devices, half of which are not covered by a Notified Body. This is particularly a concern for the SME portion of the market, which is also a challenging part of the market to sign on with Notified Bodies (unless they have a previous relationship). Notified Bodies will need to manage not only the workload leading up to May 2025 but also the overlapping workloads for May 2026 and May 2027, which need to start well in advance of the end of each transitional deadline.

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<sup>i</sup> as of October 2022, three certifications for class D IVDs had been issued;

<sup>ii</sup> 1.101 legacy devices + 87 innovative devices = 1.188;

## Conformity assessment

The length of different conformity assessment phases varies hugely. Efficiencies can be gained in reducing time-to-certification and increasing predictability of the system at every stage of conformity assessment.

This section considers findings on the timelines to issue an EU Quality Management System (QMS) certificate and EU Technical Documentation Assessment (TDA) certificate. While this section does not aim at providing a comprehensive analysis, some initial areas are proposed where conformity assessment could be made more efficient.

Only respondents who had at least one completed certificate were asked to respond to the questions in this section. Questions regarding timing asked respondents to provide the typical duration rather than actual duration per conformity assessment phase. The data given is for the typical (and therefore, the perceived) time to complete certification. It does not distinguish between the seven IVDR Notified Bodies which were available at the time of the survey; it is possible that timelines could take less or more time on average depending on the Notified Body.

In **green** are marked the timelines which are considered optimal from the manufacturer's perspective.

In **yellow** are marked timelines which are considered less efficient and indicate where improvements could be gained in optimal time-to-complete-certification.

In **red** are marked timelines which are considered excessive from the manufacturers' perspective.

It must be noted that, under the IVD Directive, the time to reach certification normally did not last more than 6 months.

### EU Quality Management System (QMS) certification

The application must pass its completeness check (at least) before the review can start; this phase can be called the 'pre-review phase'. The survey asked for the typical duration for the first and second pre-review phase:

1. Please state the typical duration in months, from the moment you **sent your submission for your very first application** until the **review start**:

- 42% 1-3 months
- 26% 4-6 months
- 32% 7-18months

2. Please state the typical duration in months, from the moment you **sent your submission for your second application** until the **review started**.

- 28% 1-3 months
- 17% 4-5 months
- 55% 7- >20 months

These survey questions above were intended to investigate whether experience gained from the first application would mean a similar or shorter duration for the second application. Some respondents reported that the second application took less time to start; however, for most the pre-review stage for the second application lasted as long or much longer than for the first application.

Various reasons were provided by respondents in their comments, which may help explain where the pre-review phase lasted longer than 3 months. They also may help explain – to a degree – why the pre-review phase for a second application lasted longer for many respondents:

- Lack of Notified Body capacity meant service was slow or interrupted.
- Additional MDCG guidance – and therefore specified requirements – were introduced since first application. This added considerably to the length of the ‘checklist’ being used by the Notified Body reviewers.
- COVID travel restrictions affected the ability of Notified Body reviewers to perform the required audits at manufacturing facilities.
- 43% of respondents indicated that a change of device category or generic device groupings was needed, following discussion with their Notified Body. This is a surprisingly large percentage of the respondents and indicates that the way in which devices are grouped for the purpose of an EU QMS conformity assessment is open to different interpretation. Changing device groupings requires rework of applications on the part of the manufacturer, takes time and may also impact on the number of technical files which are sampled by the Notified Body.

While respondents did not provide comments on the completeness of their applications, it is possible that a lack of complete documentation was a contributing factor. At the same time, one might expect that experience gained from the first application would support a better understanding of how to complete the second application; also, it seems unlikely that the significantly longer second application pre-review stage for most respondents would be explained entirely by a lack of a complete application.

3. What is the typical duration in months from **review start** until the issuance of the **recommendation for certification**?

- 28% 1-6 months
- 18% 7-9 months
- 55% 11-18 months

Notably, there is a wide variation in the time between review start and a positive recommendation by the Notified Body for certification. 55% of EU QMS certificates took between 11 and 18 months from review start until recommendation for certification.

### **EU Technical Documentation Assessment (TDA) certificates**

11% of all IVDs expected under IVDR will need a Notified Body EU TDA certificate. This is a separate workload for Notified Bodies, since such devices will also require EU QMS certification. 3.042 devices need

both EU QMS and EU TDA certification (keeping in mind that the survey data covers roughly 75% of the EU market revenue).

The survey investigated the typical duration of the pre-review phase in months. For TDA applications, no comparison was made between a first and second application.

1. Please state the typical duration in months, from the moment you **sent your application** until the **review start**:

- 41% 1-3 months
- 35% 4-6 months
- 24% 12-15 months

The time it takes between sending in the application and starting its review, are not the same as for the EU QMS application. Similarly, as for the EU QMS, there is wide variation in the time it takes for this pre-review phase, ranging from between 1-3 months and 12-15 months. However, results indicate that while variation is great, in general the pre-review phase is shorter for EU TDA than for EU QMS (55% of EU QMS applications could take between 7 and 20 months to start their review). It could still be considered as excessive for EU TDA pre-reviews to last 4-6 months, as it was reported to do in 35% of cases. It could be considered as very excessive for the pre-review stage to last for up to 12-15 months as reported by 24% of respondents.

One might expect that the pre-review phase for EU TDA should be shorter than for EU QMS as was the case 41% of the time, however it is difficult to understand why EU TDA pre-reviews would last an excessive or very excessive amount of time. The application for EU TDA is limited to the device and any accessories whereas the application for EU QMS typically covers information for multiple devices, information on the QMS, etc. Also, the slowing down of the pre-review stage cannot be attributed to discussion on grouping nor classification of devices for EU TDA as was reported to happen often for EU QMS applications. It might be attributed to lack of active work by the Notified Body during the pre-review stage or that the completeness check is complete but the review does not start, e.g. due to lack of Notified Body resources to conduct pre-reviews in a timely manner, prioritization of IVD Directive certificates during the first half of 2022 or an approach where EU TDA reviews do not start until the EU QMS conformity assessment for that device is complete.

Respondents did not provide comments on the completeness of their applications for this section; however, it is possible that a lack of complete documentation was a contributing factor in the length of the pre-review stage. It is probable that the submission of an uncomplete application would not be an explanation on its own, given the wide variation in reported duration of the EU TDA pre-review.

2. What is the typical duration in months from **review start** until the issuance of the **recommendation for certification**?

- 25% 2-6 months



- 38% 7-9 months
- 37% 10->20 months

There was enormous variation in the perceived typical duration from review start until issuance of the recommendation for certification. Only 25% of applications take up to 6 months, which was a typical timeline under the IVD Directive. 37% of applications took between 10 months and more than 20 months.

In their comments, some respondents noted that the review of technical documentation was slow and that there was lack of resources in their Notified Body to cover some or all products.

### Time to issue EU QMS and EU TDA certificates

The below tables show a calculation of number of months it takes to receive the certificate, following a positive recommendation by the Notified Body for certification. Findings for EU QMS and EU TDA certificates are considered. Issuance of the certificate is an administrative and vital part of the certification process. The assumption is made that the manufacturer should not wait more than 1 month to receive a certificate, 2-3 months is considered somewhat excessive, and more than 3 months is considered very excessive.

|                                      | Number of months to <b>issue the EU QMS certificate</b> following recommendation for certification |     |     |     |     |     |
|--------------------------------------|--|-----|-----|-----|-----|-----|
| Number of months                     | 0  | 1   | 2   | 3   | 6   | 8   |
| % manufacturers (total 10 responses) | 10%  | 10% | 10% | 20% | 40% | 10% |

|                                      | Number of months to <b>issue the EU TDA certificate</b> following recommendation for certification |    |    |     |     |    |    |
|--------------------------------------|--|----|----|-----|-----|----|----|
| Number of months                     | 1  | 2  | 3  | 4   | 6   | 8  | 11 |
| % manufacturers (total 12 responses) | 17%  | 8% | 8% | 34% | 17% | 8% | 8% |

Respondents reported a wide difference in the typical duration to receive the certificate from their Notified Body. 20% of EU QMS and 17% of EU TDA certificates are received within 1 month. However, 60% of EU QMS certificates take 3 to 6 months and 51% of EU TDA certificates take 4 to 6 months to be issued. 10% of respondents indicated it takes 8 months to receive the EU QMS certificate and 16% the EU TDA certificate.

The sometimes-long timeline for issuing certificates might be explained by limited Notified Body personnel dedicated to issuing certificates or need for improved internal procedures.

### Efficiency and predictability to be gained in conformity assessment

Wide variety in timelines at every phase of conformity assessment, point to areas where efficiencies could be gained to reduce time to reach certification and provide for a more predictable conformity assessment system.

Many respondents noted challenges which have been incorporated below. It should be noted that some comments from respondents indicated a positive overall experience with conformity assessment.

The survey findings indicate several areas where efficiencies surely could be gained for both EU QMS and EU TDA. These should not be considered as an exhaustive list:

**Pre-review phase** – more than 3 months between receiving the application and starting the review should be considered as excessive.

- The fact that respondents are reporting that 58% to 72% (EU QMS) and 59% (EU TDA) of them typically took more than 4 months to pass from application to review, should be tackled. This is also confirmation that it makes sense to invest in implementing ‘structured dialogues’ (MDCG 2022-14, action 15). By making this phase more efficient and supporting manufacturers to successfully pass their Notified Body’s application completeness check, the system could save time and resources.
- Other factors may contribute to the length of the pre-review phase, such as long or unpredictable response times from the Notified Body or manufacturer. Some respondents noted that completion of complex application forms took time.
- In principle, the manufacturer is responsible for categorisation of their devices into device category or generic device group. Changes were needed 45% of the time to the device category or generic device group during the pre-review stage. This means that applications would need to be reworked, sampling plans re-done and Notified Body resources reassigned. It also indicates that the process of grouping of devices may be open to interpretation. It could be helpful to clarify or simplify how devices are grouped or allow structured dialogues (MDCG 2022-14, action 15) to build understanding between Notified Body and manufacturer of how their devices should be grouped.

**Review phase** – time for review may vary greatly

- Survey data shows that the Notified Body is not making a difference between reviewing B and C applications. This means that the system is not investing in prioritising resources by the risk class. Evaluation of the device should be done against the general safety and performance requirements.
- In many cases, the timeline for the 2<sup>nd</sup> application increased when compared to the 1<sup>st</sup> application submitted by the same respondent. Some respondents noted that this increase was due to reviewers spending more time during the 2<sup>nd</sup> application checking requirements against a greater amount of available MDCG guidance. Given that most MDCG guidance is published in areas which are not directly related to the General Safety & Performance Requirements, this is indicative that the system resources might be re-focussed on device safety and performance rather than other areas.
- Some respondents noted there was inconsistency between reviewers including on what had been agreed as an interpretation or on number of questions per product. Such inconsistencies could perhaps be addressed by Notified Body internal practices or best practice.

- Other factors may contribute to the length of the review phase, such as long or unpredictable response times from the Notified Body or manufacturer. Some respondents commented that the review time was slow and sat with the Notified Body most of the time. Also, checklists used by Notified Bodies were seen as contributing to the length and complexity of the process.
- While respondents did not comment, it is possible that some applications were more complex or needed more attention, which contributed to longer review timelines.
- Although COVID travel restrictions are no longer in place, the ability to conduct hybrid audits may cut down on the travel time needed and improve review times.

**Issuing of certificate to manufacturer** – once there is a positive recommendation to issue a certificate, the actual issuing of the certificate by the Notified Body to the manufacturer can take months. Assignment of Notified Body resources to this activity combined with improvement in best practice, could improve efficiency.

**Overall** – comments indicate there could be improved scheduling, improved communication from the Notified Body to the manufacturer about review schedules and improved responsiveness from Notified Bodies.

The wide variety in how long the different conformity assessment phases are taking, paints a picture of a regulatory system which needs improvement in terms of predictability and efficiency. This is of concern, because the manufacturer cannot label their IVDR device, start production and make products available to their supply chain and end users until they receive certification. Uncertain timelines for conformity assessment and receiving the certificate also makes it difficult to schedule in such activities and communicate ahead to end users about the availability of devices. Long and burdensome conformity assessment times also have a severe effect on innovation and the ability to bring new IVDs to market (see next section).

## Innovation

**IVD Regulation will impact early access to innovative medical tests in Europe: there is a 28% drop in manufacturers who would prioritise the EU for first product launches.**

62% of respondents plan to prioritise the EU for a first regulatory approval, which means that the EU remains a preferred market. However, there is an almost 28% drop in respondents who would prioritise the EU market for first regulatory approval since the application of IVDR in May 2022. This is a significant change in approach. Respondents who no longer prefer the EU, plan to launch new IVDs first in the US or other jurisdictions. It can be assumed that the EU will see delays in access to new IVDs which are launched first in other jurisdictions. It is interesting that Switzerland recently decided it would change its legislation to accept devices approved by other jurisdictions (including, potentially US FDA approved devices) on its market.<sup>8</sup>

The top three options selected in answer to the question, “What impact does the IVDR have on your innovation or changes/optimization activities?”, were:

1. We expect a delay for the introduction of innovative medical products of our company in Europe
2. We are no longer making any changes/optimizations to our existing IVDs CE-marked under the IVD Directive

### 3. Running performance studies in Europe has become less predictable, costly or takes too much time

It should be noted that respondents had the possibility to report a positive, neutral or negative impact of IVDR on innovation or changes/optimization. All three of the top options selected above could be considered as indicating a negative impact (a total of eight 'negative impact' options had been provided in the survey). The first two options selected above indicate that as a result of IVDR, the IVD sector expects to invest less in bringing innovative or optimised products to Europe.

Long, unpredictable, and inefficient conformity assessment timelines pose a significant financial and resource challenge for the industry. Many respondents provided comments explaining how long and uncertain timelines contribute to 'blocking or delaying their innovation activities for Europe, for example:

- "It takes an average of 18 months between declaration of completed technical documentation and final CE-mark. This has a negative impact on the availability of new technology to patients. A further slowdown in innovation is caused due to need to direct available resources to IVDR compliance program for existing products over innovation projects."
- "As a start-up company, the impact of IVDR is high towards time to market of the new products. This is financially a very difficult situation."
- "Considering the current evaluation times, placing in the market new products is going to be almost impossible in a reasonable time. The R&D investment needs to be recuperated by the companies asap, and this is not going to happen in the current scenario."

Respondents noted considerable time from their research and development staff needed to be diverted to supporting IVDR conformity assessment for their products:

- "Our R&D Department is completely involved on tasks related to review the QMS and technical documentation according to IVDR. R&D projects on new products are on hold."
- "Some of our R&D colleagues are blocked from their work by support to the TD Assessments."
- "All of our technical resources are dedicated to paperwork, not laboratory work. The innovations will be possible once we have finished the paperwork and we had re-organised our technical team."

Running performance studies in Europe was the third top concern due to lack of predictable process, cost or time. Requirements under IVDR to notify and apply for authorisation for performance studies have been applicable since 26 May 2022. At the time this survey was run in October 2022, performance study application/notification documents had not yet been published, and the European medical devices database EUDAMED does not yet provide a centralised point for application of performance studies – instead, a patchwork of national rules applies. The requirement for Member States to coordinate their response to the application for authorisation to run a multi-country performance study only applies from 26 May 2029.

Only 624 new devices (devices which have never before had CE-marking) are expected to be brought to the EU market in the next 12-18 months. If many companies are now delaying the introduction of innovative products to Europe, then presumably this number would have been higher before IVDR (however, the survey did not investigate pre-IVDR new devices numbers).

## Conclusion

Since the first Notified Bodies started being designated, the IVD sector has made huge strides in transitioning to the IVDR. 34% of devices expected under IVDR have CE-marking. 94% of large companies and 47% of SMEs have signed on with a Notified Body and started conformity assessment for their devices.

Nonetheless, there are significant challenges which must be addressed to ensure a successful transition by May 2025, May 2026 and May 2027. This includes access to a Notified Body for SMEs, 53% of which do not yet have a contract with a Notified Body. Access to a Notified Body is a first critical step for transitioning to IVDR, and would help address an immediate critical issue, which is that 51% of Class D legacy devices are still not covered by a Notified Body agreement. Notified Bodies are only starting to issue certificates for Class D devices, and there are uncertainties around how EU Reference Laboratories could – or should – work within the assessment system once available. Notified Bodies face a considerable workload leading up to May 2025, which will overlap with the workloads needed for May 2026 (class C devices) and May 2027 (class B and class A sterile devices), since the conformity assessment for mid and lower risk devices will need to start considerably in advance of their deadlines to receive certification in time. The workload to be completed by Notified Bodies should not be underestimated; regulators and all actors will need to work together to prevent blocks or bottlenecks in certification preventing the timely transition of any IVDs.

Conformity assessment timelines – including the pre-review phase, review phase and issuance of the certificate – vary enormously in terms of time. The conformity assessment system needs improvement to become much shorter, less burdensome, and more predictable. Manufacturers need to be able to predict when they will have their certificates and can start production and communicate to their supply chain and end users. This is important to support a smooth transition of IVDs to the IVDR. It is critical for ensuring no interruption in availability of significantly updated devices and for allowing first-launch innovations to enter the European market.

One expected impact of the IVDR will be to make Europe less attractive for innovative devices. IVDR is reported by many respondents as providing resource and cost challenges which may impact those devices whose revenue is not expected to cover the cost of acquiring and maintaining CE-marking under IVDR. Long, unpredictable, and inefficient conformity assessment timelines pose a significant financial and resource challenge for the industry which can hamper the ability to bring new IVDs to market.

In the short term, full implementation of MDCG 2022-14 would help address some of the issues identified in the survey findings. The European Commission intends soon to conduct a root cause analysis of the IVDR and Medical Devices Regulation including identifying where there are blocks to innovation. It is important that this analysis and resulting recommendations address the systemic issues identified in this survey.

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<sup>1</sup> Published on 28 January 2022, [EUR-Lex - 32022R0112 - EN - EUR-Lex \(europa.eu\)](#)

<sup>2</sup> Published on 8 September 2021, [Analysing the availability of IVDs in May 2022 - MedTech Europe](#)

<sup>3</sup> Continuously updated, [List of views provided and ongoing consultations under the PECP \(europa.eu\)](#)

<sup>4</sup> Published on 26 August 2022, [MDCG 2022-14 - Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs \(europa.eu\)](#)

<sup>5</sup> Published in 2020, [The European IVD Market Statistics Report 2020](#)

<sup>6</sup> Published on 26 October 2022, [Notified bodies survey on certifications and applications \(europa.eu\)](#)

<sup>7</sup> Published in October 2022, TEAM NB position paper [Class D measures in the absence of EU Reference Laboratories - Welcome to Team NB | Team NB \(team-nb.org\)](#). This paper sets out basic approaches for Notified Bodies to conduct conformity assessment and batch release for class D devices.

<sup>8</sup> The [motion 20.3211](#) from Councilor of States Damian Müller, "*For more room for maneuver in the procurement of medical devices to supply of the Swiss population*" was accepted by the Swiss National Council on Monday 28 November, with 100 votes in favor and 79 against.

## About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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