IQVIA
CONSUMER HEALTH

Dynamics of Self-Care Medical Devices in Europe

An IQVIA Consumer Health Quickview

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Introduction

Traditionally, the European consumer health market narrative has been influenced by non-prescription medicines, also known as OTC medicines. However, the role of self-care medical devices in the market must not be neglected given their therapeutic importance and they can offer a unique self-care choice to people.

Generally, medical devices cover a wide range of diverse products that differ in form, site of application, use or route of administration, and specific medical purpose. Unlike medicinal products, medical devices do not achieve their principal mode of action by pharmacological, immunological or metabolic (PIM) means.[1] Rather, medical devices achieve their principal mode of action, for example, by physical or mechanical means.

Examples of medical devices include artificial hip joints for hip replacements, plasters, condoms, pacemakers, software apps, medical face masks and saline nasal sprays.

Self-care medical devices are similarly wide in variety and involve products commonly used for the treatment of common ailments such as cold, skin irritation, abdominal pain, as well as for contraception or prevention of the transmission of sexually transmitted diseases. The criterion that sets self-care medical devices apart from other medical devices is that they are generally available over the counter without a medical prescription and are self-administered.

Specific product examples of self-care medical devices include plasters, condoms, salt water nasal sprays, lubricating eye drops, dermal creams or gels, etc.

In a European consumer health market worth €75.2 billion in 2022, medical devices across the OTC, patient care (PAC), personal care (PEC) and nutrition categories accounted for 40% of value sales and 43% of new pack launches over the past 2 years (see Exhibit 1).

Currently the self-care medical devices market environment, like all medical devices segments, in the EU is faced with the roll-out of the EU (European Union) Medical Devices Regulation (MDR). In categories — as defined by IQVIA — such as Patient Care, medical devices make up 70% of the market value, leaving the category and therefore consumers, at a risk of shortages or unavailability of MDs resulting from MDR implementation issues. These issues we explore later in the paper.

Self-care medical devices, like all medical devices, are subject to the legal framework of the EU MDR since May 2021 which largely follows the same basic regulatory requirements as the previous Directives regulating medical devices but introduces stricter and additional requirements. At the same time, the MDR provides for a transition period allowing manufacturers under certain conditions to continue placing medical devices on the market which have been certified under the previous Directives. In fact, following an amendment of the MDR in the beginning of 2023, the transitional period has been further extended subject to meeting specific conditions until December 2027 for higher-risk devices and until December 2028 for lower-risk devices.[2]

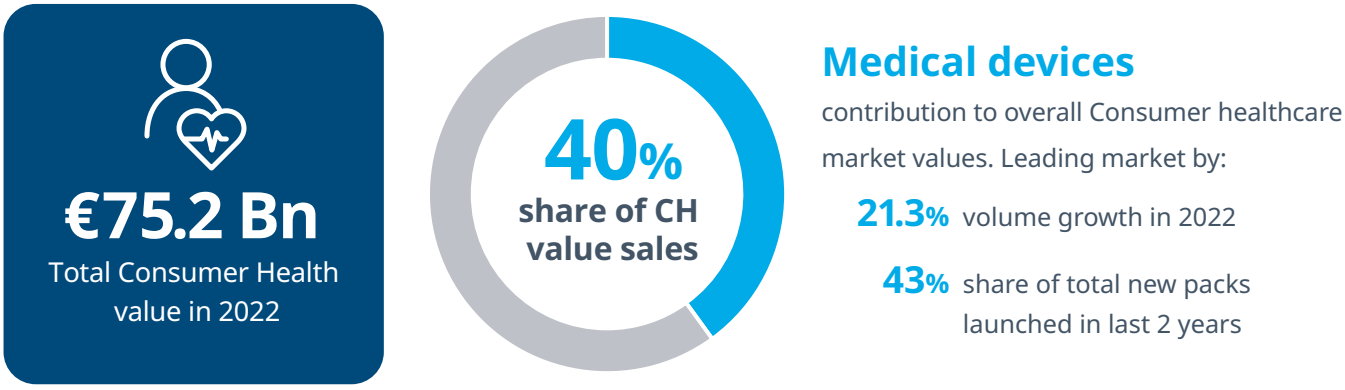
Importantly, the market data presented in the following chapters captures almost exclusively such devices which are placed on the market in accordance with transitional provisions under the MDR, i.e. they have been undergoing the conformity assessment under the previous Directives, in view of the very limited MDR certificates that were issued at the time of the study.[3] In other words, the data does not frame the market situation with regard to medical devices certified under the MDR.

Until now, it has been difficult to get a true picture of how big the self-care medical devices market is in Europe, what categories dominate the self-care medical devices landscape and where the challenges and opportunities lie.

To solve this problem and give greater clarity on this increasingly important segment of the market, IQVIA Consumer Health and the Association of the European self-care industry, the AESGP, collaborated on a project to for the first time define the market and give a clear picture of self-care medical devices in Europe.

In this paper, we will look at the market size, key categories and dominant product areas across 19 European countries (see Exhibit 5), while also addressing the opportunities and challenges that this innovative and growing sector presents. The methodology can be found in the appendix section.

Exhibit 1: Total value sales of the European consumer health market in 2022 and share of medical devices of total consumer health value sales



Source: IQVIA Consumer Health Global Insights; AESGP

Exhibit 2: European consumer health market in 2022 overview

€75.2 Bn
Total Consumer Health value in 2022

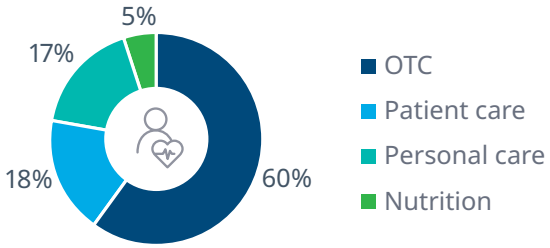
3YR CAGR TO 2022

5.2% by value
3.4% by volume

FULL YEAR 2022 GROWTH

10.5% by value
9.0% by volume

Category value share of total consumer health market 2022



Source: IQVIA Consumer Health Global Insights; AESGP

Steady as she goes: Medical devices and the European consumer health market

Post-pandemic the European Consumer Health market has grown steadily and is projected to continue this growth path in both value and volume terms over the next few years, with 'traditional' categories depressed by the pandemic — such as cough, cold, respiratory — rebounding and the increased growth rates seen in the more aspirational categories, such as vitamins, minerals and supplements (VMS), falling back but maintaining their pandemic gains (see Exhibit 2).

Given the entanglement between the wider Consumer Health market and self-care Medical Devices, it is unsurprising to see the European self-care Medical Devices market as defined by IQVIA Consumer Health following a similar growth path.

Sales of self-care Medical Devices have grown steadily in the three years to the end of 2022, contributing 40% or €19.2 billion of value sales to the wider Consumer Health market, with the highest penetration coming in the Patient Care segment.

Self-care medical devices market by segment

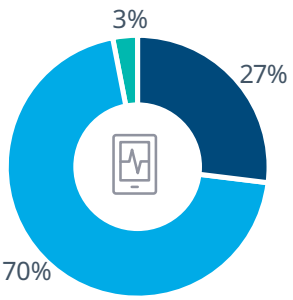
As defined by IQVIA Consumer Health, the self-care European Medical Devices Market is broken down into three categories:

- Over-the-counter (e.g.: throat lozenges; eye drops)
- Patient Care (e.g.: at home covid tests; glucose strips)
- Personal Care (e.g.: denture products; intimate hygiene)

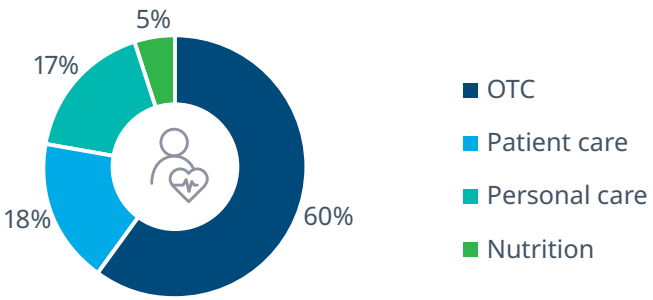
Of the three, Patient Care is by far the dominant category (see Exhibit 3), by contrast to the wider Consumer Health market where the OTC's 60% share gives it the lead.

Exhibit 3: Breakdown of the European medical device market by segment share compared to overall European consumer health market in 2022

Category value share of self-care European medical devices market 2022



Category value share of total consumer health market 2022



Source: IQVIA Consumer Health Global Insights; AESGP

Patient care

The dominant force in self-care Medical Device sales across Europe, the Patient Care category accounts for 70% of the segments sales (see Exhibit 4). Value sales in this category have been driven over the past three years by a surge in at-home Covid-19 tests which accounted for 45% of value sales in the category in 2022.

This is also reflected in the categories contribution to new product launches over the past 2 years. Across the self-care Medical Devices market in Europe, 86% of new launches have come in the Patient Care sector, driving volume growth of 25.9% in 2022. This innovation growth is backed up by already strong and growing sub-categories such as glucose monitoring tests and associated accessories.

OTC

Accounting for just over a quarter of Medical Devices value sales in Europe, the OTC Medical Devices category's 27% market share is relatively fragmented compared to Patient Care, with the leading sub-category — Eye Care — holding a 29% share of the overall category value in 2022.

Close on the heels of Eye Care, however, is the cough, cold and respiratory (CCR) category — the biggest category by share of the overall European Consumer Health market — where companies are seeing popularity of nasal sprays, throat sprays and lozenges with consumers who want fast, effective symptom relief, be it a non-prescription medicine, or a self-care medical device.

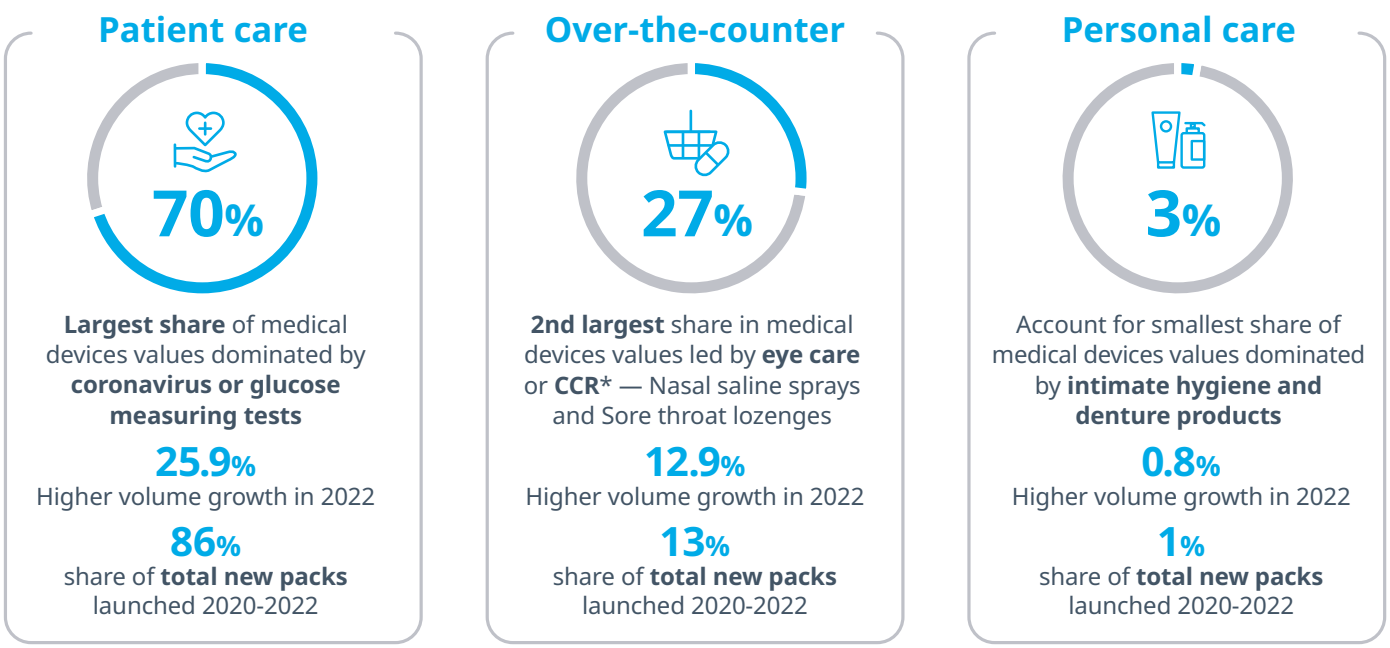
A double-digit contribution to new launches over the past two years also shows the growth in the category — especially if you consider the context of the boom in innovation in Patient Care driven by the COVID-19 pandemic.

Personal care

The Personal Care category is by far the smallest across the Medical Devices field in Europe. Accounting for just 3% of value sales in 2022 (see Exhibit 4) and with sales declining, the category is seemingly stagnating in terms of innovation, contributing just 1% of new product launches in the past 2 years to 2022.

Denture products is the dominant sub-category within Personal Care, accounting for 58% of the market, with intimate hygiene products close behind.

Exhibit 4: Overview of the patient care, OTC and personal care medical devices categories in Europe



*Total consumer health value for countries and categories in scope — €19.2 Bn. CCR: Cough, cold & respiratory products.
Source: IQVIA Consumer Health Global Insights

The geography of medical devices in Europe

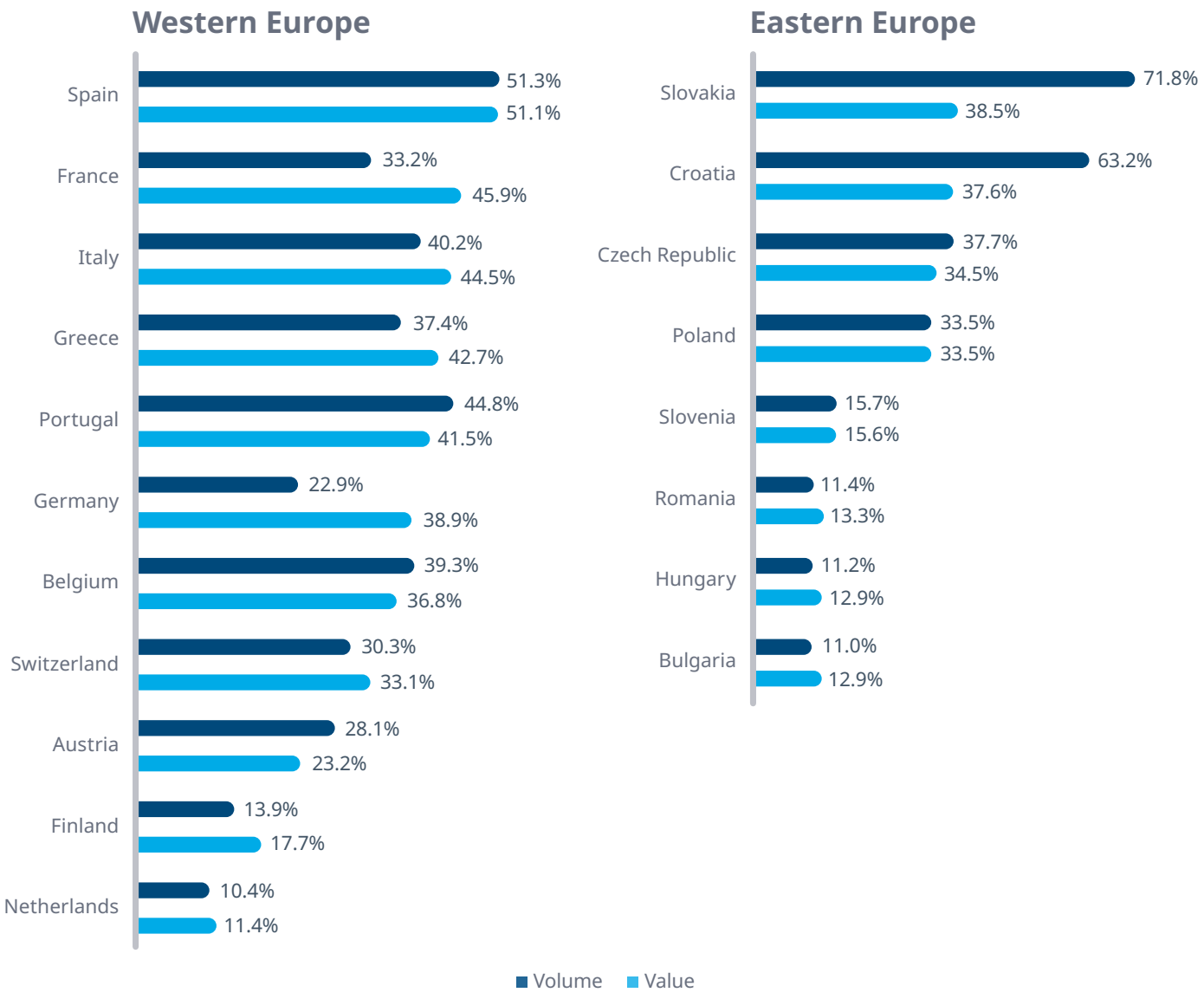
Across Europe, the share of Medical Device sales by value and by volume varies significantly, however there is a clear East-West divide. The share of the consumer health market in Western Europe held by Medical Devices is ahead of the 40% Europe-wide average, most likely thanks to the maturity of the markets in that region (see Exhibit 5).

While Western Europe can claim the highest share of medical devices sales, when it comes to volume it is Eastern Europe's Slovakia that dominates, with 71.8% of volume sales in the consumer health market in the country coming from medical devices in 2022, however, in terms of value the share plumets to just a 38.5% share.

Spain is the dominant medical devices market in terms of share in Western Europe, with its consumer health market split virtually 50/50 between medical devices and medicines/others at both the volume and value level.

Other large, mature markets in Europe — France and Italy — are also seeing a large share of the consumer health market sales, especially in value terms, going to medical devices, with France reporting medical devices value sales share of over 45% and Italy over 44%.

Exhibit 5: European medical market share by country in 2022



Source: IQVIA Consumer Health Global Insights based on MAT Q3/2022

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IQVIA Consumer Health's Global OTC Insights

Giving you the complete market picture

Trusted by 8 of the world's top 10 biggest consumer health players

Audited data that covers:

45 product categories	**80+** countries	**30k** companies	**300k** products

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Opportunity and challenge for consumer health with self-care medical devices

Taking into account the market data referred to above, self-care medical devices are certainly an established and vital part of the European Consumer Health market. It must be the objective to at least sustain the volume and growth potential of the self-care medical devices market under the MDR by creating the same favourable market conditions, notably in terms of efficiency, transparency, predictability and innovation while ensuring a high level of safety and health protection.

However, in the implementation process of the EU MDR significant challenges for all involved stakeholders have surfaced, including competent authorities, notified bodies and manufacturers, with ramifications for the industry, including the self-care medical devices market.

The challenges encountered — have led to a situation where transitioning to the MDR has been limited when taking into account recent data provided by notified bodies:

- In total, more than 24,000 certificates that were issued under the previous legal framework of the Directives need to be transitioned to the MDR.
- However, at the end of June 2023, around 13,000 MDR applications were lodged and 3,900 MDR certificates were issued.

This data has led to concerns over potential bottlenecks and even shortages of products available on the market given the fact that manufacturers must lodge an application by 26 May 2024 to benefit from the extended transition period.[4]

A particular challenge industry faces relates to the unpredictable and inefficient timelines for conformity assessments when transitioning to the MDR.

Time to obtain a MDR certificate may range between 12 to 24 months.[5] Similarly challenging is the lack of predictability in regards to notified body expectations when it comes to technical documentation in advance of the conformity assessment.

While structured dialogues between notified bodies and manufacturers before and during the conformity assessment process have been identified as a useful instrument to enhance the efficiency and predictability of the conformity assessment process under the MDR[6], it has not been implemented in practice to a great extent. As a consequence of the foregoing issues, business operators are not able to anticipate costs at the beginning of the process to obtain regulatory approval.

These key challenges for the medical device industry as a whole raise doubts as to whether the presented figures relating to self-care medical devices can be indeed transferred to the MDR regulatory framework. Only if these challenges are properly addressed by streamlining the certification process under the MDR to allow for an efficient, predictable and transparent transition to the MDR, will it create the adequate regulatory conditions for the self-care medical devices market.

Innovation in the MDR era

However, despite this uncertainty, there are several potential benefits associated with the marketing of products as medical devices provided the product characteristics allow for it, notably with regard to the mode of action, including for example:

- Direct access to the whole EU market plus the countries participating in the European Economic Area (Iceland, Liechtenstein and Norway) upon successful completion of the applicable conformity assessment procedure under the MDR;
- Without taking into account the regulatory approval process, the cost associated with developing a product as a medical device can may be lower when compared to other product categories — although not without the same risks when it comes to commercial success.

Furthermore, as the data shows, these products are highly popular among consumers seeking rapid, efficient symptom relief.

Conclusion

In conclusion, while the implementation of the new Medical Device Regulation (MDR) in the EU presents significant challenges for the consumer health industry, it also opens the door to exciting opportunities. The self-care medical device market is a testament to innovation and consumer empowerment, playing a pivotal role in enabling individuals across Europe to proactively manage their health.

Addressing the current hurdles, such as the unpredictability and inefficiency of conformity assessments, is essential. By fostering structured dialogues between notified bodies and manufacturers, the industry can gain clarity and predictability in technical documentation requirements.

This proactive approach will not only streamline the transition to the MDR but also enhance the industry's ability to anticipate costs more effectively. Embracing these changes will allow manufacturers to focus on harnessing the potential of digital health technologies, which are rapidly transforming the healthcare landscape.

Ultimately, by navigating these challenges, the self-care medical devices sector is poised to continue its trajectory of growth and innovation, ensuring swift market access for new products and reinforcing its crucial role in supporting the health and well-being of consumers across Europe.

Appendix

Study methodology

1

Extrapolate the IQVIA historical consumer health sales **for missing channels** (refer to the next slide) by factoring in available internal benchmarks

2

Leveraged local data to **estimate medical device** share (value & volume) of *Germany*, *Belgium*, *Poland*, and *Italy* at selected CHC 1 & 2 category level

3

Mapped the remaining countries in-scope with *Germany*, *Belgium*, *Poland*, and *Italy* based on similar regulatory framework in agreement with AESGP team

4

Applied estimated ballpark for medical devices share to **remaining countries** as per their mapping to derive medical device sales

Global definition of consumer health— Four major segments adding up to $700Bn+

01

Over the counter

Treatment and/or prevention
Eg. Cough/cold, pain relief, digestive health and vitamins/minerals

02

Personal care

Beauty and/or hygiene
Eg. Skin, beauty care products, oral hygiene

03

Nutrition

Infant & adult nutrition
Eg. Infant and adult formulas, diabetic food, nutritional products

04

Patient care

Medical devices & wound care
Eg. Blood glucose test strips, blood pressure monitors, wound care, stoma care, incontinence care

References

1. See also the legal definition of “medical device” in Article 2 (1) of the MDR.
2. Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.
3. See Dashboard monitoring the availability of medical devices and in-vitro diagnostic medical devices in the European Union
4. See MDCG 2022-11 Rev. 1
5. See Notified Bodies Survey on certifications and applications (MDR/IVDR): PowerPoint Presentation (europa.eu)
6. Please see point 15 in the MDCG position paper 2022-14: Notified body capacity and availability of medical devices and IVDs.

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