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How to Select the Proper EU Notified Body for your Medical Device Organization

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Objective

The objective of this White Paper is to provide information to manufacturers who intend to market medical devices in the European Union (EU) and/or Canada with guidance on identifying, selecting and approving an accredited EU Notified Body in accordance with the regulatory requirements of current medical device directives, including:

- Medical Devices Directive 93/42/EEC (MDD)
- Active Implantable Medical Devices Directive 90/385/EEC (AIMD)
- In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVDD)
- European Medical Device Regulation 2017/745 (MDR)
- European In Vitro Device Regulation 2017/746 (IVDR)
- Medical Device Single Audit Program (MDSAP)

Introduction

The EU's MDD/IVDD and MDR/IVDR regulations, as well as Canadian Medical Devices regulations, require legal medical device and IVD manufacturers to contract with a government accredited/recognized auditing organization (AO) to perform conformity assessment procedures. These assessments include manufacturers' quality management systems (QMS) and product-specific technical documentation for conformance to state-of-the-art safety and clinical performance requirements.

Accredited and/or recognized organizations determine manufacturers' legal compliance to a country's specific medical device regulation, European ordinances and/or future European medical device regulations. The national European Competent Authorities (CA) have accredited certain private sector organizations to perform conformity assessment procedures against current directives, national laws and regulations.

From 26 May 2020 forward, EU medical device conformity assessments will only be performed against the EU MDR (2017/745) on behalf of EU country-specific CAs, supervised by the European Commission (EC) in Brussels, Belgium. These government accredited/designated private sector organizations are termed "Notified Bodies," and they must have a certification office in a European member state country. In case of non-European member state countries such as Turkey, Switzerland and Australia, the Notified Body status is based on a 'so called' Mutual Recognition Agreement (MRA). Additionally, if a Notified Body is also recognized by Health Canada to perform MDSAP audits, they are identified as an MDSAP auditing organization. Medical device manufacturers may select any auditing organization from the lists published by the United States Food & Drug Administration (U.S. FDA) government website, which may be found here.

As with any business partnership, selecting the right organization to serve as a manufacturer's EU Notified Body and/or Canadian MDSAP assessment body is of significant strategic importance and should not be taken lightly. For example, changing a Notified Body can be a time-consuming and very expensive endeavor. One of the requirements of the current medical device directives and EU regulations is that unique Notified Body CE Mark identification numbers must appear on all products, packaging and labeling after successful completion of the conformity assessment process. Consequently, changing a Notified Body requires significant cost and may present a delay due to the transition process, not to mention the risk of market

removal and relabeling of all concerned products and accompanying product documentation.

Overview: EU Notified Bodies

As previously outlined, Notified Bodies are independent European private sector organizations accredited or designated by EU national government organizations (in the future, the European Commission will act on behalf of Brussels for EU MDR). A national, or EC Commission accreditation/designation, grants Notified Bodies the right to perform conformity assessments against the respective European directives, and national member state laws and regulations against the EU MDR. Following a successful conformity assessment procedure, companies will sign their draft and issue their Declaration of Conformity (DoC) to the respective provisions of the directives assessed. This allows legal device manufactures the right to label assessed medical products with a CE Mark, including the four-digit Notified Body identification number for commercial distribution.

Not all Notified Bodies are equally accredited to perform conformity assessments to every directive and all device categories.

Keep in Mind: Not all Notified Bodies are equally accredited to perform conformity assessments to every directive and all device categories. The accreditation scope and available expertise differs widely among Notified Bodies and may change over time. However, the need for a Notified Body with multiple accreditations is only an issue if a legal manufacturer maintains a product portfolio regulated by more than one directive or regulation (e.g., the AIMD and MDD). Some Notified Bodies also only maintain restricted designations to specific types of products, product risk classifications or specific types of conformity assessment procedures. Thus, not all Notified Bodies are able to provide a full range of conformity assessment services that manufacturers may require presently, or in the future, for business objectives.

Larger Notified Body organizations maintain offices outside of Europe, often within the United States, China, Japan and South America. Smaller Notified Bodies, which are typically European-based only, do not necessarily have representatives fluent in English or other languages. The above decision criteria should be taken into account during the initial Notified Body identification and selection process.

Accredited Notified Body Statistics

Currently, the European Nando Database lists 93 accredited Notified Bodies for the three (3) main medical device and IVD directives:

- 58 Notified Bodies authorized to perform MDD assessments
- 13 Notified Bodies authorized to perform AIMDD assessments
- 22 Notified Bodies authorized to perform IVDD assessments

Keep in Mind: There are only six (6) Notified Bodies accredited for all three (3) medical device directives. There is currently one (1) designated Notified Body listed for the EU-MDR 2017/745—this Notified Body is accredited against all other medical device/IVD directives and is also listed as an AO for MDSAP.

Best Practice: To verify if a selected Notified Body of choice maintains all required conformity assessment pathways and/or product-specific technical competence expertise, select the legislation of concern from the provided list (e.g. 93/42/EEC Medical Devices) and select either the Procedure/Article/Annex, product or technical competence fields to learn more. (The scope of current accreditations against medical device and other directives and restrictions in medical product categories is published and updated by the European Committee for each Notified Body, found here.)

Medical Device Single Audit Program (MDSAP)

The MDSAP has been developed to allow authorized auditing organizations to conduct a single audit of a medical device manufacturer that will be accepted by all five (5) regulatory authorities participating in the program:

- Therapeutic Goods Administration of Australia (TGA)
- Brazilian Agência Nacional de Vigilância Sanitária (ANVISA)
- Health Canada (HC)
- United States Food and Drug Administration (U.S. FDA)
- Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA)

Keep in Mind: An MDSAP compliance audit does not include a European conformity assessment audit against the above listed regulatory directive and/or regulation requirements. At current, the European Commission has not adopted the MDSAP audit program for EU conformity assessments; rather, they are performed in addition to an MDSAP audit, but may utilize the same audit team and audit date.

The recognition of an EU Notified Body as an MDSAP AO to perform QMS certification audits under the MDSAP is required by HC for Canadian marketing authorizations.

The following types of device classes are exempt from Notified Body involvement with/or without MDSAP recognition prior to commercial distribution in the European Economic Area and Canada:

- Manufacturers who distribute only Class I devices in Canada
- Manufacturers who distribute only MDD Class I devices in Europe, except for sterile devices, devices with measuring function and reusable devices
- Manufacturers who distribute only IVDD self-certified devices, unless the devices are used for self-testing or are listed in Annex II of the IVDD

Manufacturers who wish to market their Class II, III and IV devices in Canada are **required to undergo a QMS assessment to the most current ISO 13485:2016 QMS standard**, including regulatory compliance to the most updated Canadian Medical Devices Regulations (CMDR) (SOR/98-282). Therefore, manufacturers were required to submit MDSAP certificates by **31 December 2018** to legally sell devices in the Canadian market. However, HC has recently decided to relinquish enforcement actions against manufacturers without certificates if they demonstrate proof of conducting an MDSAP audit by the same deadline.

To legally sell devices in Canada until a MDSAP certificate is received, manufacturers transitioning to the new guidelines must hold a valid ISO 13485 certificate under the Canadian Medical Devices Conformity Assessment System. These ISO certificates **must be valid from 31 December 2018 or 1 January 2019**, when the program became operational (if issued by a MDSAP auditing organization). They must have also already made contractual arrangements with a recognized AO to undergo a full MDSAP certification audit. (HC's model differs from other geographical regions covered by the MDSAP consortium—such as Australia, Brazil, Japan and the U.S.—in that it is currently the only one that strictly requires MDSAP certificates to make determinations on Class II, III, and IV device licenses.)

Best Practice: If Canada is a viable commercial market for an organization, or a manufacturer wishes to continue selling medical products in Canada, it is a best practice to narrow the Notified Body selection to the potential candidates authorized to perform MDSAP and Notified Body audits under the EU directives and that are designated under future medical device regulations.

At current, there are only a handful of MDSAP auditing organizations that are also part of an EU Notified Body organization. Please see the ***List of EU Notified Bodies & MDSAP Auditing Organizations*** provided in Attachment A. A current list of all MDSAP auditing organizations, including contact information, is also provided here.

Selecting an MDSAP auditing organization that is not recognized as a Notified Body is not recommended as manufacturers may have to coordinate and plan redundant assessments, resulting in increased costs, extended timelines and scheduling complications.

Notified Body: Identification and Selection Process

The initial Notified Body identification and selection process should include the following steps, which are further described in the following paragraphs:

- Determine the company representatives responsible for the identification and selection process
- Prepare a brief summary of your company and its medical devices manufactured and under development
- Organize a list of products of obtained or intended marketing authorizations
- Prepare a prioritized list of desired/required Notified Body requirements
- Narrow a list of potential candidates if your company is selling, or intends to sell, medical products in Canada or to Notified Bodies with HC recognition as MDSAP auditing organizations
- Create a list of potential Notified Body/MDSAP auditing organization candidates to be assessed

Best Practice: If your company distributes, or is planning to distribute, commercial medical devices of Class II and/or higher in Canada, it is strongly advised to select a Notified Body that is also a HC recognized MDSAP auditing organization. HC requires MDSAP certificates to make determinations on Class II, III and IV device marketing authorization licenses already issued or planned to be issued in 2019.

Manufacturers who wish to market their Class II, III and IV devices in Canada are required to undergo a QMS assessment to the most current ISO 13485:2016 QMS standard, including regulatory compliance to the most updated Canadian Medical Devices Regulations (CMDR) (SOR/98-282).

Notified Body: Selection and Assessment Team

The identification and selection process should be spearheaded by representatives from the regulatory and quality functions within an organization. Other supporting roles that may provide valuable input include:

- Manufacturing/Operations
- Purchasing
- Clinical
- Engineering

Senior management should also be involved in the selection process and participate in the final decision.

The identification, selection and approval process of qualified Notified Body conformity assessment services follows Quality Management Policies and Procedures (SOPs) for Purchasing as set forth in ISO 13485 Section 7.4.

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Start-up medical device companies, or organizations transitioning to a new Notified Body candidate, may want to solicit the assistance of an experienced external consulting organization, such as NAMSA, to support and facilitate a structured process to ensure the best-fit Notified Body for your organization's current and future objectives will be selected.

Preparation of Company Summary Information

Prepare a brief presentation of your company and its product portfolio—this presentation will help facilitate internal and external communications, and narrows the field of potential candidates (many Notified Bodies are not accredited to assess all product categories). The presentation should include, at a minimum:

- Brief company presentation (e.g., organizational chart, business locations and number of employees)
- Overview of existing regulatory product clearances and approvals (e.g. US-FDA 510(k), TGA, etc.)
- Overview of current product portfolio and products under development
- Overview of product development timelines for product(s) under development
- Overview of manufacturing and processes performed in-house and outsourced
- Preliminary EU and Canadian device classification(s) and justification
- Preferred conformity assessment pathways (if applicable)

This summary also helps the prospective Notified Body candidates to clearly understand and identify an organization's specific regulatory certification requirements and timelines to prepare an accurate and engaging proposal.

Keep in Mind: Notified Body organizations calculate the cost of EU conformity assessments, including duration of audits and assessment of technical documentation, by the following parameters:

- Number of employees
- Design and manufacturing sites to be audited
- Product risk classification(s)
- Special manufacturing processes
- Product portfolio to be assessed
- Content and complexity of technical and clinical information to be assessed (e.g. drug/device combination products, in-vivo products or derivatives)

The better a Notified Body candidate comprehends a company's medical device product portfolio, development/manufacturing processes and product-specific expertise required for conformity assessments, the more likely it is that a proposal will meet organizational expectations in estimated timelines and costs.

For more information on Notified Body conformity assessment costs, device classifications and the different EU conformity assessment methods specified by the directives and the EU MDR, please contact NAMSA.

Notified Body: Requirements

It is suggested that medical device manufacturers prepare a priority list of essential requirements important for the EU Notified Body selection process. This list may include the following, but is not limited to:

- Scope of accreditation for product and assessment routes under the current directives and regulations
- Reasonable assurance of accreditation status under the EU-MDR 2017/745 and likelihood of continuing and supporting a re-certification process in accordance with the MDR
- HC recognition as an MDSAP auditing organization (if applicable)
- Office locations within your company's time zones
- Availability of qualified local auditors for a QMS assessments
- Availability of medical device technology specialists that possess expertise within your product portfolio
- Availability of clinical reviewers relevant to your product portfolios medical application(s)/intended uses/indications for use (e.g., cardiovascular, orthopedics, neurology, etc.)
- Business languages (e.g., English, French, German or others)
- Business culture (e.g., response time, customer service, complaint handling, transparency, etc.)
- Notified Bodies internal organization and business structure (e.g. organizational chart, decision processes)
- Availability of Notified Body client references for evaluation purposes

Best Practice: If your company's only option is to select an organization to serve as both a Notified Body and an HC recognized MDSAP auditing organization, the selection of potential Notified Body candidates is narrowed considerably and will likely remain so throughout the incoming MDR regulatory framework.

Notified Body: First Steps

As a first step, manufacturers should review the appropriate Notified Body lists and eliminate non-accredited candidates to assess your organization's product types and technologies. For example, some MDD Notified Bodies may only review class IIa non-invasive devices; if your company's device is a cardiovascular catheter, these particular Notified Bodies would not be qualified.

Keep in Mind: Individual past Notified Body experiences or referrals from professional peers from different companies and product portfolios could be misleading. Due to the changing regulatory framework in Europe, the roles and responsibilities of Notified Body organizations are significantly changing. In order to meet the strict organizational and competency requirements of the incoming MDR 2017/745, remaining Notified Bodies will no longer be an accepting, business-friendly economic partner. The prescriptive MDR requirements, combined with shifting responsibilities and closer oversight from national Competent Authorities over the EU Commission may not leave much room for deviating interpretation, proprietary

Notified Body policies and procedures—resulting in rather benign conformity assessments (as perhaps experienced in the past).

If possible, review readily available guidance documents from the EU Commission, Notified Body websites and trade journal articles. Please see a list of NAMSA MDR/IVDR planning resources here.

Notified Body: The Interview Process

Once a manageable list of Notified Body candidates is developed (three to five candidates at most), these organizations should be contacted to conduct initial screening interviews—these can be accomplished via phone, video conference or face-to-face meetings. Use the presentations and requirements listed previously, in addition to your well-structured QMS service provider selection process, to gather valuable information so each interviewed Notified Body organization can be compared equitably and without bias.

Keep in Mind: The initial contact is most likely a sales/marketing representative—they may not know the answers to each of your questions. However, the following should be assessed throughout the interview process:

- Willingness to carefully listen to your questions and concerns
- Reasonable efforts to connect you to someone who is able and willing to answer your questions
- Timeliness of follow-up and feedback
- Quality of feedback/response

Be mindful of Notified Body marketing responses emphasizing past legacy, quick solutions and general marketing statistics as each EU conformity assessment is different. Contracting with a Notified Body is typically done to establish a strategic long-term partnership. Make sure Notified Body representatives are able to carefully listen to your requests and allow sufficient time to provide focused responses to facilitate a meaningful dialog.

Though important, **try to avoid focusing on cost of service and delivery timelines during the first candidate interviews**. Notified Body organizations are required to collect very detailed manufacturing and product technology information prior to delivering a well thought-out conformity assessment proposal. Instead, request information material, an application package and a client reference list.

Due to the changing regulatory framework in Europe, the roles and responsibilities of Notified Body organizations are significantly changing.

The information material should provide the most current information regarding the eligible conformity assessment process, scope of Notified Body designation, special healthcare technology experience and expertise, as well as helpful business background about the Notified Body/MDSAP Auditing Organization (e.g. business locations, number of employees, etc.).

The application package should include comprehensive, easy-to-understand forms, including information about your company as a business entity, its current product portfolio, manufacturing information and status of QMS implementation.

If possible, request a copy of a sample contractual regulatory service agreement form, including terms and conditions. Notified Body organizations are private sector entities and typically work under a legal entity and for-profit. Contractual agreements, as well as Terms and Conditions, vary among European Notified Bodies.

Be aware of hidden fees and contingencies as well as incomprehensive breach of contract clauses. Ensure you understand the legal and national requirements, as well as consequences prior to signing a Notified Body regulatory service agreement.

Get a good idea of how each candidate Notifed Body organization interacts with your company as a paying client by making careful observations of the personnel's professionalism. Some areas that might be worthy of note include:

- Is there a dedicated contact person assigned to handle a manufacturer's project? If so, is there a back-up in case this contact is on leave?
- Does the organization view questions as criticisms or honest inquiries?
- How well does the organization seem to understand your company, its product portfolio and business operations?
- Are alternative conformity assessment solutions being recommended or proposed?
- Is the Notified Body organization genuinely interested in learning about your company and are they supportive of a successful conformity assessment?
- How well can the Notified Body explain its internal organization and its processes (e.g., to render a decision)?

It is important to render a final decision not exclusively on hard factual evidence and rankings, but also based on feedback from the internal Notified Body selection team.

Notified Body: The Final Selection Process

When the above information has been obtained for each Notified Body candidate, the responsible Regulatory Assurance/Quality Assurance individual(s) should review and assess the information and propose the final candidate. The criteria used in making this final selection may be ranked by keeping in mind who best meets all of the following requirements:

- Current and future accreditations and recognitions
- Current and future authorizations for product scopes and risk classifications
- Availability of expertise and knowledge of product technology, clinical application and processes
- Understanding of your company's needs and expectations
- Appropriate response time
- Reasonable predictability for assessment timelines and costs
- Maintenance of a supportive and appropriate means for customer service
- Reasonable cost of service (both initial and maintenance)

Oftentimes, the selection list can easily be narrowed down to two strong candidates. It may be beneficial to have one final face-to-face meeting with both Notified Body organizations and let them know where you stand in the decision process. Discussion should include a summary of your evaluation process to observe how each Notified Body candidate responds.

At this point in the process, you may be able to meet the responsible person(s) likely managing your project, and if possible, the individuals who may be involved with your conformity assessment. However, it is important to render a final decision not exclusively on hard factual evidence and rankings, but also based on feedback from the internal Notified Body selection team. How likely are they to engage with the Notified Body personnel that were met in person or communicated with? Is this conducive to a long-term partnership? It is important to find out what other team members think and recognize—different employees will bring varying and important perspectives.

Following the final selection, it is recommended not to rush into a final commitment (e.g., executing a legally binding service contract immediately). Problems can arise unexpectedly that might make it impossible to work with the selected Notified Body organization. If you must make a commitment at this point, be sure the contractual agreement between your company and the Notified Body includes a reasonable exit clause.

Conclusion

Notified Bodies are private sector organizations designated by an EU country to assess the conformity against applicable legislation of regulated healthcare products before being placed on the market. Put simply, **they can make or break successful European market access for promising healthcare technologies**.

The selection process for a Notified Body candidate is a management priority and closely aligned with medical product portfolio and business priorities. The transition from the European Directives Member State-driven framework to an EU Commission-driven regulatory framework for devices sold in Europe makes the identification and selection process of a Notified Body more complex than in the past. For example, there is a significant decline of accredited and recognized Notified Bodies that can meet different and new EU regulatory conformity assessment requirements, as well as product safety and performance requirements. Therefore, it is even more critical to make a sustainable and strategic Notified Body decision for current healthcare products and future healthcare technology developments.

The outlined Notified Body selection process does not necessarily guarantee the best possible outcome, but the proposed process and best practice advice returns an improved understanding of Notified Body regulatory conformity assessment needs and expectations. **A diligent selection process should return a professional and strategic regulatory partnership to assist with current and future business objectives**.

Attachment A:

List of EU Notified Bodies & MDSAP Auditing Organizations

This list is current as of March 2019. The table includes the names of the organizations, the Notified Body number (NB#), if applicable, and authorization to perform conformity assessments of medical devices against the regulatory conformity assessment requirements of the MDR, MDD, AIMD, IVDD and MDSAP as indicated by an X.

NOTE: To verify accuracy of the below information, please access the official European Commission Nando website provided here. The U.S. FDA MDSAP may be found here.

NB#	Organization/Legal Entity	Location(s)	MDR	MDD	AIMD	IVDD	MDSAP
0044	TÜV NORD CERT GmbH	Germany USA		X	X		
0050	National Standards Authority of Ireland (NSAI)	Ireland USA		X	X	X	X
0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy		X	X		
0068	MTIC InterCert S.r.l.	Italy		X			
0086	BSI Assurance UK Ltd.	UK	X	X	X	X	
0088	LLOYD'S REGISTER QUALITY ASSURANCE LTD	UK		X		X	
0120	SGS United Kingdom Limited	UK		X		X	X
0123	TÜV SÜD Product Service GmbH	Germany USA		X	X	X	
0124	DEKRA Certification GmbH	Germany		X			
0197	TÜV Rheinland LGA Products GmbH	Germany USA		X	X	X	
0297	DQS Medizinprodukte GmbH	Germany		X			X
0318	AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS	Spain		X		X	
0344	DEKRA Certification B.V. (aka KEMA Quality B.V.)	Netherlands USA		X	X	X	X
0373	ISTITUTO SUPERIORE DI SANITA	Italy		X		X	
0402	SP Sveriges Tekniska Forskningsinstitut AB	Sweden		X			
0413	INTERTEK SEMKO AB	Sweden		X			

NB#	Organization/Legal Entity	Location(s)	MDR	MDD	AIMD	IVDD	MDSAP
0425	ICIM S.P.A.	Italy		X			
0426	ITALCERT SRL	Italy		X			
0459	G-MED Laboratoire national d'essais	France		X	X	X	X
0476	KIWA CERMET ITALIA S.P.A	Italy		X			
0477	Eurofins Product Testing Italy S.r.l.	Italy		X			
0481	ECM-ZERTIFIZIERUNGS-GESELLSCHAFT FÜR MEDIZINPRODUKTE IN EUROPA MBH	Germany		X			
0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGS GESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany		X	X		
0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany		X		X	
0494	SLG PRÜF UND ZERTIFIZIERUNGS GMBH	Germany		X			
0537	Eurofins Expert Services Oy	Finland		X		X	
0543	Presafe Denmark A/S	Denmark		X		X	
0546	CERTIQUALITY S.R.L. Instituto Di Certificazione Della Qualita	Italy		X			
0598	SGS FIMKO OY	Finland		X			
0633	ERLIN CERT PRÜF- UND ZERTIFIZIERSTELLE FÜR MEDIZINPRODUKTE GMBH	Germany		X			
0653	NATIONAL EVALUATION CENTER OF QUALITY AND TECHNOLOGY IN HEALTH S.A.- EKAPTY L S.A."	Greece		X			
0681	Eurofins Product Service	Germany		X			
0805	THERAPEUTIC GOODS ADMINISTRATION	Australia (MRA)		X			
0843	UL INTERNATIONAL (UK) LTD	UK		X		X	
1011	Országos Gógyszerészeti és Élelmezés-egészségügyi Intézet Eszközminősítő és	Hungary		X		X	

NB#	Organization/Legal Entity	Location(s)	MDR	MDD	AIMD	IVDD	MDSAP
1014	ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV, s.p.	Czech Republic		X	X		
1023	INSTITUT PRO TESTOVÁNI A CERTIFIKACI, a.s.	Czech Republic		X		X	
1250	Schweizerische Vereinigung für Qualitätsicherung und Managementsysteme	Switzerland (MRA)		X			
1254	QS Zürich AG	Switzerland (MRA)		X			
1282	ENTE CERTIFICATIONE MACCINES SRL	Italy		X			
1293	EVPU a.s.	Slovakia				X	
1304	SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ	Slovenia		X			
1370	BUREAU VERITAS ITALIA S.P.A.	Italy		X			
1434	POLSKIE CENTRUM BADAN I CERTYFIKACJI	Poland		X	X	X	
1639	SGS Belgium NV	Belgium		X			
1783	TURKISH STANDARDS INSTITUTION (TSE)	Turkey		X		X	
1912	DARE! Certifications	Netherlands		X			
1936	TUV Rheinland Italia SRL	Italy		X			
1984	Kiwa Belgelendirme Hizmetleri A.Ş.	Turkey		X			
2195	Szutest Teknik Kontrol ve Belgelendirme Hizmetleri Ticaret Limited Şirketi	Turkey		X			
2265	3EC International a.s.	Slovakia		X		X	
2274	TUV NORD Polska z.o.o.	Poland		X			
2282	DQS Polska Sp. z.o.o.	Poland		X			
2292	UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi Sanayi ve Ticaret Limited Sirketi	Turkey		X			
2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary		X	X	X	
2460	DNV GL Presafe AS	Norway		X			

NB#	Organization/Legal Entity	Location(s)	MDR	MDD	AIMD	IVDD	MDSAP
2764	Notice Belgelendirme, Muayene ve Denetim Hizmetleri Anonim Şirketi	Turkey		X			
2767	BSI Group The Netherlands B.V.	Netherlands		X	X	X	
2803	G.F.I. Health Technology Certification Ltd.	Cyprus		X			
	TÜV Rheinland of North America, Inc.	USA					X
	TÜV SÜD America Inc. (also operating as TÜV America Inc.)	USA					X
	TÜV USA, Inc. affiliated with TÜV Nord	USA					X
	UL Medical and Regulatory Services UL, LLC	USA					X
	QMI-SAI Canada Limited	Canada					X
	NSF Health Services Certification L.L.C.	USA					X
	Intertek Testing Services NA Inc.	USA					X
	Lloyd's Register Quality Assurance Inc.	USA					X
	BSI Group America Inc.	USA					X

Acronyms	
AIMDD	Active Implantable Medical Device Directive
AO	Auditing Organization
CA	Competent Authority
CAB	Conformity Assessment Body
CE	Conformité Européene
EEC	European Economic Community
EU	European Union
EUDAMED	European Database on Medical Devices
FDA	US-Federal Drug Administration
HC	Health Canada
IVDD	In-Vitro Diagnostic Device Directive
IVDR	In-Vitro Diagnostic Device Regulation
ISO	International Organization for Standardization
MDD	Medical Device Directive
MDSAP	Medical Device Single Audit Program
MDR	Medical Device Regulation
MRA	Mutual Recognition Agreement
NANDO	New Approach Notified and Designated Organisations - Information System
NB	Notified Body
QMS	Quality Management System
TGA	Therapeutic Goods Administration in Canada

References

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance)
3. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended
4. Council Directive 98/79/EEC of 27 October 1998 concerning in-vitro diagnostic devices as amended
5. Council Directive90/385/EEC of 20 June 1990 concerning active implantable medical devices as amended
6. MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization IMDRF MDSAP Working Group (18 September 2014)
7. U.S. FDA MDSAP Website https://www.fda.gov/medicaldevices/internationalprograms/mdsappilot/
8. EC NANDO Website http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main

About NAMSA

NAMSA is a Medical Research Organization (MRO®), accelerating medical device product development through integrated laboratory, clinical and consulting services. Driven by our regulatory expertise, NAMSA's MRO® Approach plays an important role in translational research, applying a unique combination of disciplines—consulting, regulatory, reimbursement, preclinical, toxicology, microbiology, chemistry, clinical, and quality—to move clients' products through the development process, and continue to provide support through commercialization to post-market requirements anywhere in the world. NAMSA operates 13 offices throughout North America, Europe, the Middle East and Asia, and employs 1,000 highly-experienced laboratory, clinical research and regulatory consulting Associates. Visit us at www.namsa.com.

About the Authors

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Stephan Buttron currently serves as NAMSA's Senior Product Development Strategist. Mr. Buttron has over 20 years' experience in achieving EU, U.S. FDA and other international regulatory medical device approvals and registrations. He has provided global consulting services on regulatory strategy development to medical device manufacturers regarding least burdensome pathways for 510(k)/PMA and MMD-CE mark applications. He has successfully managed FDA pre-submission meetings for Investigational Device Exemption (IDE) pathways with multiple FDA specialty branches. Stephan is considered a key industry thought leader on risk management, and has provided multiple training sessions to medical device manufacturers on structured risk management process per EN ISO 14971 & EU MDD 93/42 as amended with directive 2007/ 47. Mr. Buttron has also provided countless educational opportunities to international organizations regarding medical device design and development issues related to ISO 13485 & EU MDD 2007/47 compliance.

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Alex Laan currently serves as NAMSA's Principal Regulatory Consultant. He has a total of 20 years' experience within the IVD/medical device industries, with 12 years dedicated to working for a leading EU Notified Body. While acting as Principal Certification Manager at DEKRA Certification BV/Notified Body (Arnhem, Netherlands) and Lead Assessor at KEMA Quality, he oversaw regulatory and Notified Body strategies for both large multinational and start-up organizations. He developed a proprietary Quality Management System (QMS) while acting as IVD QA/RA Manager at Meddens Diagnostics/IBL Hamburg that allowed the organization to register their full range of assays in the EU (Annex II List B) and with the U.S. FDA. Mr. Laan is an active member of EU Notified Body IVD working groups, TEAM-NB and serves as a direct contact for EU Competent Authorities and the EMA regarding implementation of the forthcoming MDR and IVDR.

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