



# **Dragon Sourcing**

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*Your Tailored Approach to Emerging Markets*

## **Newsletter on PPE**

*Classification of PPE and CE Certification Process in EU*

**April, 2020**



# Reports in EU of some Chinese PPEs with invalid CE mark

- In the past few days, the unprecedented high demand of PPEs in EU and the Chinese government's decision to allow restart export of PPEs resulted in many new Chinese suppliers exporting to the EU, some of them not being traditionally manufacturers of PPEs.
- European Safety Federation has found some suspicious CE certificates for PPE & Medical Devices from China indicating that either the products are not certified by right authorities (Notified Body) or supplier is exporting using forged or fake documents.
- Some notable products that the European Safety Federation found are:
  - CE certification by notified bodies such as ICR Polska, CELAB and ECM, that are indeed notified bodies, but not for the PPE products that the supplier was distributing in EU.
  - Documents with layout similar as those of Notified Body BSI are confirmed to be Fake by BSI itself.
  - 'Declaration of Conformity' on letter head of Institutes Nova Certificates & GTS are confirmed by the concerned Organisations to be False.
  - Also some documents are issued by different Chinese Institutes and not by an EU authorized notified body.
- A CE Mark is mandatory for PPE and Medical Device products sold in the EU.
- The following pages have more information on CE mark and the process to obtain it





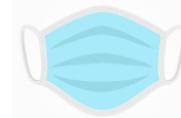
# Product Classification

## Personal Protective Equipment (PPE)



- Personal protective equipment are defined as products that protect the wearer from injury or infection.
- We have identified and qualified suppliers of the following products under PPE category:
  - Gloves
    - Nitrile
    - Vinyl
    - Latex
  - Masks
    - N95 Masks and Respirators
  - Isolation Gowns
  - Eye protection & Face Shields

## Medical Device (MD)



- A Medical Devices are product or equipment intended generally for a medical use. They are mainly intended to use for patient's protection.
- Medical Devices are classified in to 3 classes
  - Class I- Low Risk
    - **Surgical Face Mask (3 Ply, etc)**
    - Elastic Bandages
    - Manual stethoscopes, etc.
  - Class II (a & b)- Medium Risk
    - Syringes
  - Class III- High Risk
    - Pacemaker, Deep Brain Stimulators,
    - High-frequency ventilators, etc.
- We have identified and qualified suppliers of surgical face masks falling under this category



# Product Classification by EU Regulation

## EU Regulation 2016/425

- **Regulation (EU) 2016/425** of 9 March 2016 on personal protective equipment (the PPE regulation) and repealing Council Directive 89/686/EEC covers the design, manufacture and marketing of PPE.
- It defines legal obligations to ensure that PPE on the EU internal market provides the highest level of protection against risks.
- The following PPE products in focus in this report will be governed by this regulation:
  - N95 Masks & Respirators
  - Gloves (Nitrile, Latex & Vinyl)
  - Isolation Gowns and Eye Protection

## EU Regulation 2017/745

- **Regulation (EU) 2017/745** of 5 May 2017 on Medical Devices and Accessories, 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.
- It ensures the design, manufacture and functioning of the Medical Devices to meet required safety standards.
- Products under this regulation are classified in 3 different classes according to Risk criteria. Surgical Masks including 3 Ply masks that are classified under Class I devices will be governed by this regulation

- All PPE and MD products sold in the EU will fall in either one of the two regulations above
- Depending on usage intension, these products will have to meet required standards of the Regulation, for e.g., if Surgical mask is to be used for wearer's protection, it must meet PPE standards as well
- EU Safety Commission requires all products sold under these regulations must have certified CE mark
- The authorized bodies to evaluate and certify the products are called Notified Bodies, which are listed on Nando list of the EU Safety commission. Only these bodies have the authority to certify for CE mark



# CE Mark & Process for Certified CE Mark

- Products sold in the EU region should conform to EU Regulations pertaining to that product. Only products that meets the regulation standard are allowed to use the certified CE mark by particular Notified Body.
- The CE mark (Conformité Européenne) certifies that the product has met EU health, safety & environmental requirements, which ensures consumer and workspace safety.
- The CE marking Process :

The Declaration must include:

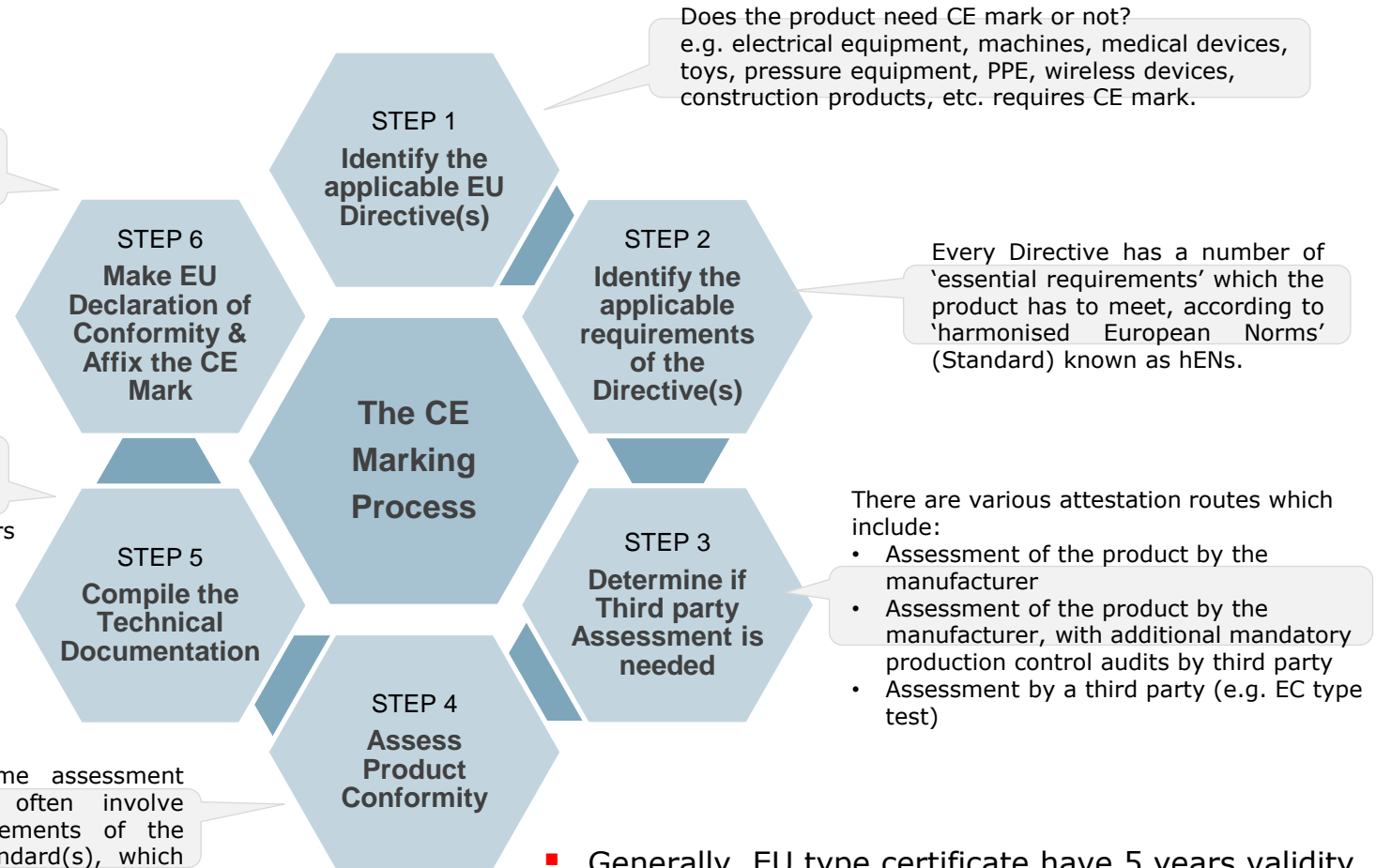
- Details of the manufacturer
- Product details
- List of applied CE Directives & standards
- Declaration for the product meeting requirements
- And more depending on product & corresponding regulation

Technical documentation will usually include:

- Description & Drawings
- Bill of materials
- Test reports and/or assessments
- Specifications & Instructions

Documentation must be available for 10 years after the manufacture of the last unit.

This usually involves some assessment and/or testing. It will often involve ensuring that the requirements of the applicable harmonised standard(s), which were identified in step 2, have been met.



- Generally, EU type certificate have 5 years validity



# PPE Regulation (EU)2016/425

- Regulation (EU) 2016/425 of 9 March 2016 on personal protective equipment (the PPE regulation).
- PPE classification under Regulation (EU) 2016/425:
  - Routes for PPE CE mark:

### Category 1:

- (a) Superficial Mechanical Injury
- (b) Contact with cleaning materials of weak action or prolonged contact with water
- (c) Contact with hot surfaces not exceeding 50 °C
- (d) Damage to the eyes due to exposure to sunlight (other than during observation of the sun)
- (e) Atmospheric conditions that are not of an extreme nature. E.g. Safety gloves, glasses, shoes, head gear, etc.

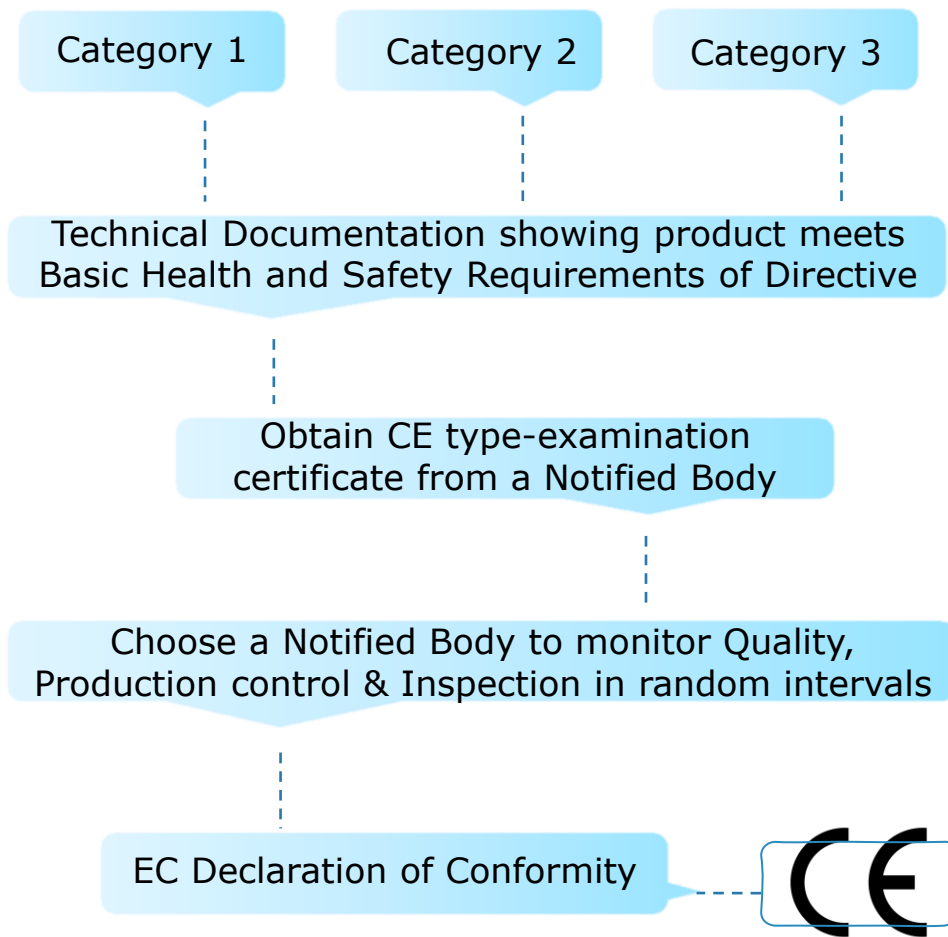
### Risk Categories of PPE

### Category 2:

Risks other than those listed in Category 1 & 3

### Category 3:

- (a) substances and mixtures which are hazardous to health
  - (b) atmospheres with oxygen deficiency
  - (c) harmful biological agents
  - (d) ionizing radiation
  - (e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C
  - (f) low-temperature environments the effects of which are comparable to those of an air temperature of - 50 °C or less
  - (g) falling from a height
  - (h) electric shock and live working
  - (i) Drowning
  - (j) cuts by hand-held chainsaws
  - (k) high-pressure jets
  - (l) bullet wounds or knife stabs
  - (m) harmful noise
- E.g. Chemical resistant suit, gloves, boots, air hose, lanyard, anchor, hook, face shield, helmets, Hearing protector, safety glasses, safety suit, etc.





# Notified Bodies (for Regulation (EU) 2016/425)

- EU requires a third party, independent body called “Notified Body” to evaluate whether the product complies with relevant legislation.
- The Notified Bodies that are accredited by the European Commission to conduct this evaluation are listed and updated on the official Nando website (recent full list is mentioned here).
- A manufacturer/supplier for PPE must only approach the accredited notified bodies for Regulation (EU) 2016/425 to certify CE mark.
- Notified Bodies for Regulation (EU) 2016/425 are:

Body Type	Name	Country
NB 0465	A.N.C.I. - SERVIZI S.R.L. - SEZIONE CIMAC (CENTRO ITALIANO MATERIALI APPLICAZIONE CALZATURIERA)	Italy
NB 0099	AENOR INTERNACIONAL, S.A. (Unipersonal)	Spain
NB 0333	AFNOR Certification	France
NB 2754	ALIENOR CERTIFICATION	France
NB 0511	ALLGEMEINE UNFALLVERSICHERUNGSANSTALT - SICHERHEITSTECHNISCHE PRÜFSTELLE	Austria
NB 0302	ANCCP Certification Agency Srl	Italy
NB 0082	APAVE SUDEUROPE SAS	France
NB 0161	ASOCIACION DE INVESTIGACION DE LA INDUSTRIA TEXTIL	Spain
NB 2779	ASOCIACIÓN PARA LA PROMOCIÓN, INVESTIGACIÓN, DESARROLLO E INNOVACIÓN TECNOLÓGICA DE LA INDUSTRIA DEL CALZADO Y CONEXAS DE LA RIOJA	Spain
NB 0334	ASQUAL	France
NB 2790	ASSOCIAÇÃO PORTUGUESA DOS INDUSTRIAIS DO CALÇADO, COMPONENTES, ARTIGOS DE PELE E SEUS SUCEDÂNEOS	Portugal
NB 1524	BIMEO VIZSGALO ES KUTATO-FEJLESZTO KFT.	Hungary
NB 0086	BSI Assurance UK Ltd	UK
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2004	Bureau Veritas Consumer Products Services Germany GmbH	Germany
NB 2834	CCQS Certification Services Limited	Ireland
NB 1105	CCQS UK LTD	UK
NB 0493	CENTEXBEL (WETENSCHAPPELIJK EN TECHNISCH CENTRUM VAN DE BELGISCHE TEXTIELNIJVERHEID - DIVISIE GENT)	Belgium
NB 1437	CENTRALNY INSTYTUT OCHRONY PRACY - PANSTWOWY INSTYTUT BADAWCZY (CIOP-PIB)	Poland
NB 0159	CENTRO NACIONAL DE MEDIOS DE PROTECCION-INSTITUTO NACIONAL DE SEGURIDAD E HIGIENE EN EL TRABAJO	Spain
NB 0624	CENTRO TESSILE COTONIERO E ABBIGLIAMENTO SPA	Italy
NB 0530	CERTOTTICA SCARL	Italy
NB 2766	CITEVE Certificação Unipessoal Lda	Portugal
NB 0497	CSI SPA	Italy
NB 0075	CTC	France

Body Type	Name	Country
NB 0158	DEKRA Testing and Certification GmbH	Germany
NB 0340	DGUV Test Prüf- und Zertifizierungsstelle Elektrotechnik Fachbereich Energie Textil Elektro Medienerzeugnisse der Deutschen Gesetzlichen Unfallversicherung e.V. (DGUV)	Germany
NB 0299	DGUV Test Prüf- und Zertifizierungsstelle Fachbereich Persönliche Schutzausrüstungen der Deutschen Gesetzlichen Unfallversicherung e.V. (DGUV)	Germany
NB 0418	DGUV Test Prüf- und Zertifizierungsstelle Fachbereich Rohstoffe und chemische Industrie der Deutschen Gesetzlichen Unfallversicherung e.V. (DGUV)	Germany
NB 0556	DGUV Test Prüf- und Zertifizierungsstelle Nahrungsmittel und Verpackung Fachbereich Nahrungsmittel der Deutschen Gesetzlichen Unfallversicherung e.V. (DGUV)	Germany
NB 0196	DIN CERTCO GESELLSCHAFT FÜR KONFORMITÄTBEWERTUNG MBH	Germany
NB 0098	DNV GL SE	Germany
NB 2008	DOLOMITICERT S.C.A.R.L.	Italy
NB 1401	Department of Textiles Physical-Chemical Testing of Textile Institute of State Scientific Research Institute Center for Physical Sciences and Technology	Lithuania
NB 0363	Deutsche Prüf- und Zertifizierungsstelle für Land- und Forsttechnik	Germany
NB 1883	ECS European Certification Service GmbH	Germany
NB 2475	EUROINSPEKT EUROTTEXTIL d.o.o. Odjel za certifikaciju	Croatia
NB 0477	Eurofins Product Testing Italy S.r.l.	Italy
NB 2789	FINANCIERE POURQUERY	France
NB 0514	FLEETWOOD TEST HOUSE, BLACKPOOL AND THE FYLDE COLLEGE	UK
NB 0200	FORCE Certification A/S	Denmark
NB 2233	GÉPTESZT Termelőszközökét Felülvizsgáló és Karbantartó Kft.	Hungary
NB 0555	HOHENSTEIN LABORATORIES GmbH & Co. KG	Germany
NB 1322	IBS - Institut für Brandschutztechnik und Sicherheitsforschung GmbH	Austria
NB 0164	IDIADA AUTOMOTIVE TECHNOLOGY S.A.	Spain
NB 1523	INNOVATEX Textile Engineering and Testing Institute Co.	Hungary
NB 2849	INSPEC International B.V.	Netherlands
NB 0194	INSPEC International Ltd.	UK
NB 0160	INSTITUO ESPAÑOL DEL CALZADO Y CONEXAS, ASOCIACION DE INVESTIGACION	Spain
NB 0073	INSTITUT DE RADIOPROTECTION ET DE SÛRETÉ NUCLÉAIRE	France





# Notified Bodies for Regulation (EU) 2016/425

Body Type	Name	Country
NB 0078	INSTITUT NATIONAL DE LA PLONGEE PROFESSIONNELLE	France
NB 1023	INSTITUT PRO TESTOVÁNI A CERTIFIKACI, a. s.	Czech Republic
NB 1493	INSTITUTE OF OCCUPATIONAL SAFETY	Slovenia
NB 1475	INSTYTUT TECHNOLOGII BEZPIECZENSTWA MORATEX	Poland
NB 2575	INTERTEK Italia S.p.A.	Italy
NB 0865	ISET Srl Unipersonale	Italy
NB 0376	ISTITUTO ITALIANO SICUREZZA DEI GIOCATTOLEI SRL	Italy
NB 0426	ITALCERT SRL	Italy
NB 0362	ITS Testing Services (UK) Ltd	UK
NB 0072	Institut Français de Textile et de l'Habillement (IFTH)	France
NB 0121	Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA) Prüf- und Zertifizierungsstelle im DGUV Test	Germany
NB 2756	Institutul National de Cercetare Dezvoltare pentru Protectia Muncii - I.N.C.D.P.M. "Alexandru Darabont"	Romania
NB 1809	Institutul National de Cercetare-Dezvoltare pentru Securitate Miniera si Protectie Antiexploziva	Romania
NB 2534	Instytut Technologii Tekstylnych CERTEX Sp. z o.o.	Poland
NB 2198	KR HELLAS LTD.	Greece
NB 0162	LEITAT Technological Center - Acondicionamiento Tarrasense	Spain
NB 1556	MADI es TARSA Technical, Safety and Service Ltd. Testing Laboratory	Hungary
NB 1080	MATERIALPRÜFUNGSANSTALT UNIVERSITÄT STUTTGART	Germany
NB 2474	MIRTA-KONTROL d.o.o.	Croatia
NB 2841	MNA LABORATUVARLARI SANAYI TICARET LIMITED ŞİRKETİ	Turkey
NB 0068	MTIC InterCert S.r.l.	Italy
NB 1247	NSBIV AG (Zertifizierungsstelle SIBE Schweiz)	Switzerland (MRA)
NB 0193	PFI - PRÜF-UND FORSCHUNGSINSTITUT PIRMASENS E.V.	Germany
NB 1463	POLSKI REJESTR STATKOW S.A.	Poland
NB 1974	PZT GmbH	Germany
NB 0498	RICOTEST	Italy
NB 0474	RINA Services S.P.A.	Italy
NB 0402	RISE Research Institutes of Sweden AB	Sweden
NB 0404	RISE SMP SVENSK MASKINPROVNING AB	Sweden
NB 0321	SATRA	UK
NB 0598 (ex-0403)	SGS FIMKO OY	Finland

Body Type	Name	Country
NB 0120	SGS United Kingdom Limited	UK
NB 1439	SIEC BADAWCZA LUKASIEWICZ - INSTYTUT PRZEMYSŁU SKORZANEGO	Poland
NB 1435	SIEC BADAWCZA ŁUKASIEWICZ - INSTYTUT WŁOKIENICTWA	Poland
NB 0518	SIRA CERTIFICATION SERVICE	UK
NB 1015	STROJIRENSKY ZKUŠEBNI USTAV s.p.	Czech Republic
NB 0338	Shirley Technologies Limited, trading as BTTG	UK
NB 1246	Suva CERTIFICATION	Switzerland (MRA)
NB 0516	Sächsisches Textilforschungsinstitut e. V. - An-Institut der Technischen Universität Chemnitz	Germany
NB 0396	TEKNOLOGISK INSTITUT - Certificering & Inspektion	Denmark
NB 1726	TESTEX AG , Schweizer Textilprüfinstitut	Switzerland (MRA)
NB 1021	TEXTILNÍ ZKUŠEBNÍ ÚSTAV, s.p.	Czech Republic
NB 1783	TURKISH STANDARDS INSTITUTION (TSE)	Turkey
NB 0560	Telefication B.V. also trading under the names Kiwa Telefication and Kiwa EMC	Netherlands
NB 0408	TÜV AUSTRIA SERVICES GMBH	Austria
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0336 (ex-1750)	TÜV Rheinland Nederland B.V.	Netherlands
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany
NB 0843	UL INTERNATIONAL (UK) LTD	UK
NB 2821	UL International (Netherlands) B.V.	Netherlands
NB 1771	UNIVERSITÄT STUTTGART INSTITUT FÜR FÖRDERTECHNIK UND LOGISTIK	Germany
NB 2163	Universal Certification and Surveillance Service Trade Ltd. Co.	Turkey
NB 2369	VIPO a. s.	Slovakia
NB 1296	VUTCH - CHEMITEX spol. s r.o.	Slovakia
NB 1019	VVUU, a.s.	Czech Republic
NB 2594	Vias Institute	Belgium
NB 2452	Vojenský technický ústav, s. p.	Czech Republic
NB 1024	Vyzkumny ustav bezpecnosti prace, v. v. i.	Czech Republic
NB 2019	West Yorkshire Materials Testing Service (West Yorkshire Joint Services)	UK
NB 2777	satra Technology Europe Ltd	Ireland
NB 0534	ÖTI - Institut für Ökologie, Technik und Innovation GmbH	Austria
NB 2762	Öffentliche Prüfstelle für das Textilwesen der Hochschule Niederrhein GmbH	Germany

- Some of the Notified Bodies under 2016/425 have global presence like TÜV SÜD, Intertek, etc. They can evaluate and certify in the countries they are present.





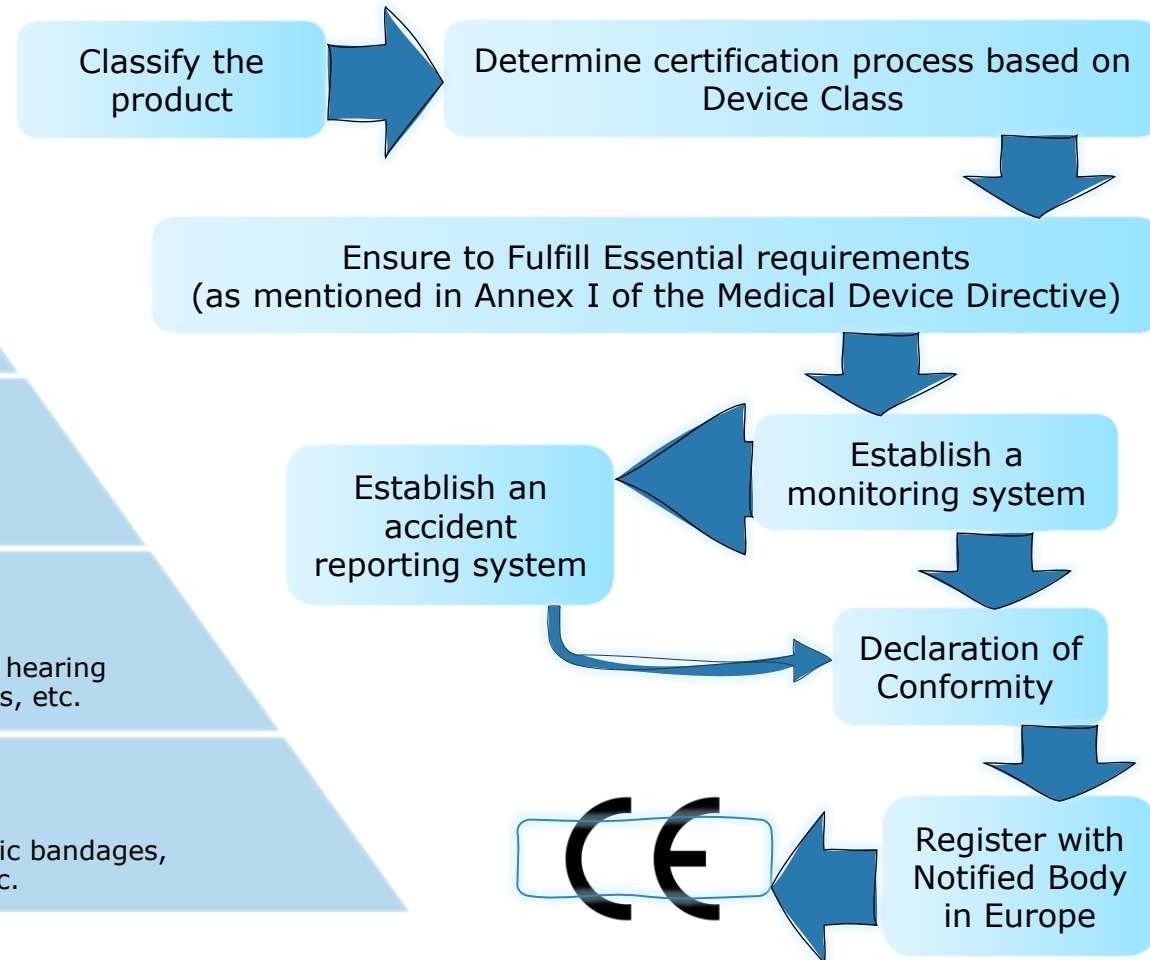
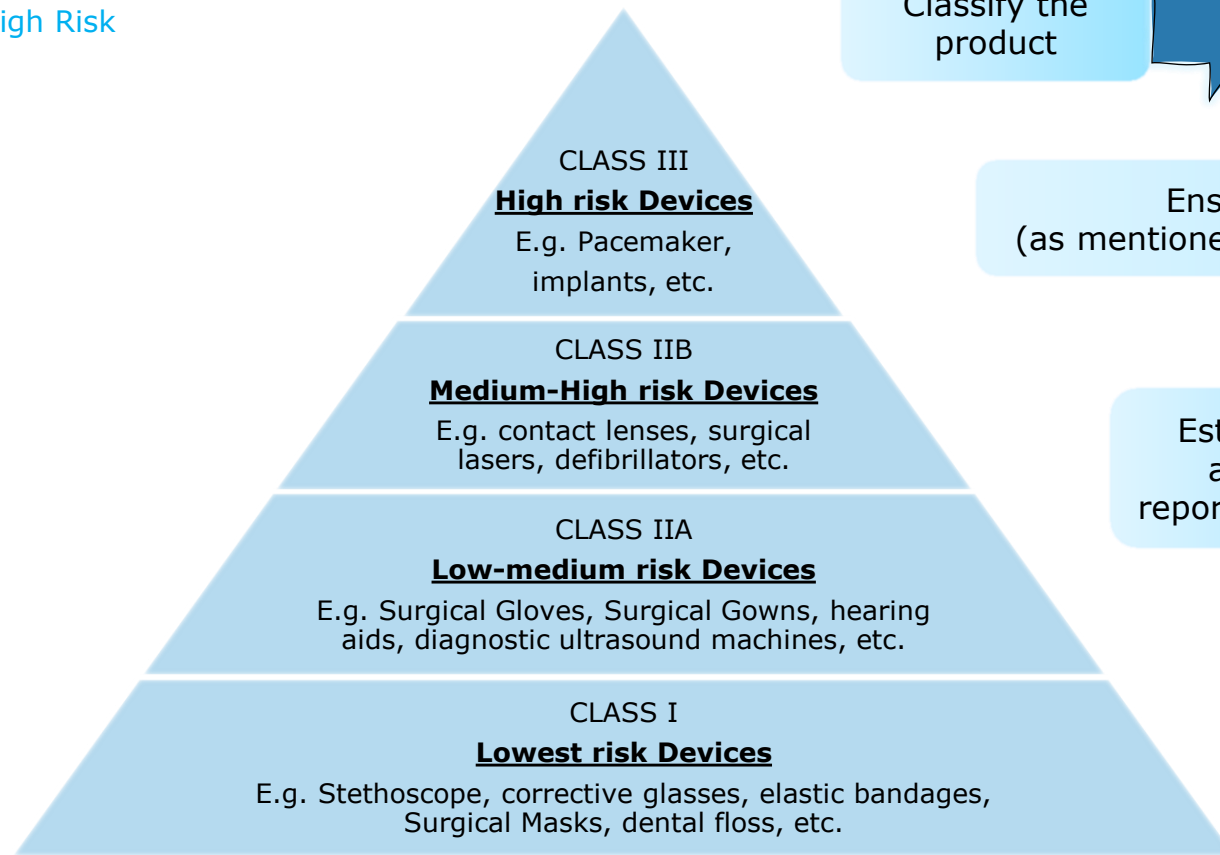
# Medical Devices Regulation (EU) 2017/745

- **Regulation (EU) 2017/745** published on 5 May 2017 on Medical Devices and Accessories.
- Medical devices in the EU have to undergo a **conformity assessment** to demonstrate that they meet legal requirements to ensure they are safe and perform as intended by Notified body.
- Medical Devices can be classified as:

High Risk



Low Risk





# Notified Bodies for Regulation (EU) 2017/745

- Notified Bodies under Regulation (EU) 2017/745 are:

<u>Body Type</u>	<u>Name</u>	<u>Country</u>
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 1912	DARE!! Services B.V.	Netherlands
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 2460	DNV GL Presafe AS	Norway
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany



# How do we check CE compliance of suppliers?

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- As part of RFI response, suppliers send CE compliance documents and details of the notified body that evaluated and passed the supplier
- We contact the notified body and verify the authenticity of the compliance documents and certificates
- There is no central database for CE marks and Notified body certificates. Only notified body who issued the certificate can validate it



# Contact Us

## EUROPEAN Offices

Dragon Sourcing **Paris**  
57 Rue de La Malmaison  
92140 Clamart France  
Tel: **+33 (0)1 46 10 36 70**  
Fax: +33 (0)1 46 10 41 14  
Email: [bonjour@dragonsourcing.com](mailto:bonjour@dragonsourcing.com)

Dragon Sourcing **Spain**  
Carrer de Biada 5, Bajos.,  
08012 Barcelona, Spain  
London, W1U 6PZ, UK  
Tel: **+ 34 689 87 09 02**  
Email: [hello@dragonsourcing.com](mailto:hello@dragonsourcing.com)

Dragon Sourcing **Russia**  
Aleksandri Monahovoi St 98, block 1  
Moscow, 108801, Russia  
Email: [hello@dragonsourcing.com](mailto:hello@dragonsourcing.com)

Dragon Sourcing **Turkey**  
Yuzuncu Yil Mah. Prof Erdal Inonu Cad..  
No 10 Dalgic Sitesi B Blok Daire 30  
Nilufer Bursa, Turkey  
Tel: +90 505 506 86 76  
Email: [merhaba@dragonsourcing.com](mailto:merhaba@dragonsourcing.com)

Dragon Sourcing **South Africa**  
94 Princess Avenue, Benoni 1500,  
Gauteng Province, South Africa  
Tel: **+27 61 128 1949**  
Email: [contact.hello@dragonsourcing.com](mailto:contact.hello@dragonsourcing.com)



## NORTH AMERICAN Office

Dragon Sourcing **Houston**  
4532 Plantation Colony Dr  
Missouri City, TX 77459  
Phone: **832- 406-0281**  
Email: [hello@dragonsourcing.com](mailto:hello@dragonsourcing.com)

## LATIN AMERICAN Offices

Dragon Sourcing **Brazil**  
Rua Funchal, 538, 2 andar  
04551-060, Vila Olímpia, São Paulo, Brazil  
Tel: +55 11 9 9595 0405  
Email: [ola@dragonsourcing.com](mailto:ola@dragonsourcing.com)

Dragon Sourcing **Mexico**  
PROLONGACION VASCO DE QUIROGA #  
4800, Tower II Office 102 Floor 1  
SANTA FE CUAJIMALPA, MEXICO CITY,  
Phone +52 312 1217217  
Email: [hello@dragonsourcing.com](mailto:hello@dragonsourcing.com)

## ASIAN Offices

Dragon Sourcing **Shanghai**  
Suite 1502-1503, Jin Tian Di International Mansions  
998, Renmin Road – Shanghai, 200021, P.R.China  
Tel: **+86 21 61 41 39 55**  
Fax: +86 21 61 41 39 66  
Email: [contact.asia@dragonsourcing.com](mailto:contact.asia@dragonsourcing.com)

Dragon Sourcing **Hong Kong**  
10/F Guangdong Investment Tower,  
148 Connaught Road Central, Hong Kong  
Tel: **+852 91 80 40 57**  
Fax: +852 25 80 24 26  
Email: [contact.asia@dragonsourcing.com](mailto:contact.asia@dragonsourcing.com)

Dragon Sourcing **Vietnam**  
Room A1.03, Hoang Anh River View  
37 Nguyen Van Huong Street, Thao Dien Ward.,  
District 2, HCM City, Vietnam  
Tel: **+84 28 6685 3589**  
Email: [hello@dragonsourcing.com](mailto:hello@dragonsourcing.com)

Dragon Sourcing **Saudi Arabia**  
Thiqa Bldg. 2nd Flr., Othman Ibn Affan Road (Exit 7  
King Abdullah Road Al-Waha District  
Riyadh, Kingdom of Saudi Arabia  
Tel: +966 11 810 2252  
Email: [hello@dragonsourcing.com](mailto:hello@dragonsourcing.com)

Dragon Sourcing **India**  
Suite 1502, Sorrento,  
Veera Desai Road,  
Andheri West, Mumbai – 400053  
India  
Email: [contact.india@dragonsourcing.com](mailto:contact.india@dragonsourcing.com)



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**Komal Patel**

Email: [komal.patel@dragonsourcing.com](mailto:komal.patel@dragonsourcing.com)