MedTech Europe

Notified Bodies listed in NANDO under MDR and IVDR, including designation codes

Regulation (EU) 2017/746 IVDR	Amount of Notified Bodies Notified	1	2
	Notified Body Name & Number	**DEKRA GmbH NB 0124**	**BSI UK NB 0086**
	Notification date	10/10/2019	28/10/2019
	NANDO	Link to NANDO	Link to NANDO
A. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
1. Devices intended to be used for blood grouping			
IVR CODE	Devices intended to be used to determine markers of the specific blood grouping systems to ensure the immu- nological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration		
IVR 0101	**Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)]**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0102	**Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0103	**Devices intended to determine markers of the Kell system [Kel1 (K)]**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0104	**Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0105	**Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR CODE	Other devices intended to be used for blood grouping		
IVR 0106	**Other devices intended to be used for blood grouping**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
2. Devices intended to be used for tissue typing			
IVR CODE	Devices intended to be used for tissue typing		
IVR 0201	**Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compati- bility of blood, blood components, cells, tissue or organs that are intended for transfusion or trans- plantation or cell administration**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0202	**Other devices intended to be used for tissue typing**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
3. Devices intended to be used for markers of cancer and non-malignant tumours			

IVR CODE	Devices intended to be used for markers of cancer and non-malignant tumours except devices for human genetic testing		
IVR 0301	**Devices intended to be used in screening, diagnosis, staging or monitoring of cancer**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0302	**Other devices intended to be used for markers of cancer and non-malignant tumours**	Annex IX(I) Annex IX(II) Markers for the predisposition of tumor diseases	Annex IX(I) Annex IX(II) Annex XI
4. Devices intended to be used for human genetic testing			
IVR CODE	Devices intended to be used for human genetic testing		
IVR 0401	**Devices intended to be used in screening/confirmation of congenital/inherited disorders**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR CODE	Devices intended to be used for human genetic testing		
IVR 0402	**Devices intended to be used to predict genetic disease/disorder risk and prognosis**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0403	**Other devices intended to be used for human genetic testing**	-	Annex IX(I) Annex IX(II) Annex XI
5. Devices intended to be used to determine markers of infections/immune status			
IVR CODE	Devices intended to be used for the screening, confirmation, identification of infectious agents or determination of immune status		
IVR 0501	**Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0502	**Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0503	**Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0504	**Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0505	**Devices intended to be used to grow/isolate/identify and handle infectious agents**	Annex IX(I) Annex IX(II) limited to devices to be used to identify and handle infectious agents	Annex IX(I) Annex IX(II) Annex XI

IVR 0506	**Other devices intended to be used to determine markers of infections/immune status**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures			
IVR CODE	Devices intended to be used for a specific disease		
IVR 0601	**Devices intended to be used for screening/confirmation of specific disorders/impairments**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0602	**Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0603	**Devices intended to be used for screening, confirmation/ determination, or monitoring of allergies and intolerances**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0604	**Other devices intended to be used for a specific disease**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR CODE	Devices intended to be used to define or monitor physiological status and therapeutic measures		
IVR 0605	**Devices intended to be used for monitoring of levels of medicinal products, substances or biological components**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0606	**Devices intended to be used for non-infectious disease staging**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0607	**Devices intended to be used for detection of pregnancy or fertility testing**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0608	**Devices intended to be used for screening, determination or monitoring of physiological markers**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0609	**Other devices intended to be used to define or monitor physiological status and therapeutic measures**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
7. Devices which are controls without a quantitative or qualitative assigned value			
IVR CODE	Controls without a quantitative or qualitative assigned value		
IVR 0701	**Devices which are controls without a quantitative assigned value**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0702	**Devices which are controls without a qualitative assigned value**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
8. Class A devices in sterile condition			

IVR CODE	Class A devices in sterile condition		
IVR 0801	**Devices referred to in point 2.5 (rule 5), under a), of Annex VIII to Regulation (EU) 2017/746**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0802	**Instruments intended specifically to be used for in vitro diagnostic procedures referred to in point 2.5 (rule 5), under b), of Annex VIII to Regulation (EU) 2017/746**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
IVR 0803	**Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746**	Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
II. **HORIZONTAL CODES**			
1. In vitro diagnostic devices with specific characteristics			
IVS CODE	In vitro diagnostic devices with specific characteristics		
IVS 1001	**Devices intended to be used for near-patient testing**	Yes	Yes
IVS 1002	**Devices intended to be used for self-testing**	Yes	Yes
IVS 1003	**Devices intended to be used as companion diagnostics**	Yes	Yes
IVS 1004	**Devices manufactured utilising tissues or cells of human origin, or their derivatives**	Yes	Yes
IVS 1005	**Devices in sterile condition**	Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), sterilisation with hydrogen peroxide, sterilisation with liquid chemical sterilising agents	Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
IVS 1006	**Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017/746)**	Yes	Yes
IVS 1007	**Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes (point 1.6 of Annex VIII to Regulation (EU)**	Yes	Yes
IVS 1008	**Instruments, equipment, systems or apparatus**	Yes	Yes
IVS 1009	**Software that are devices in themselves including software apps, software for data analysis, and for defining or monitoring therapeutic measures**	Yes	Yes
IVS 1010	**Devices incorporating software/utilising software/controlled by software**	Yes	Yes
2. *In vitro diagnostic devices for which specific technologies are used*			
IVT CODE	In vitro diagnostic devices for which specific technologies are used		

IVT 2001	**In vitro diagnostic devices manufactured using metal processing**	Yes	Yes
IVT 2002	**In vitro diagnostic devices manufactured using plastic processing**	Yes	Yes
IVT CODE	In vitro diagnostic devices for which specific technologies are used		
IVT 2003	**In vitro diagnostic devices manufactured using non-metal mineral**	Yes	Yes
IVT 2004	**In vitro diagnostic devices manufactured using non-metal non-mineral processing (e.g. textiles, rub- ber, leather, paper)**	Yes	Yes
IVT 2005	**In vitro diagnostic devices manufactured using biotechnology**	Yes	Yes
IVT 2006	**In vitro diagnostic devices manufactured using chemical processing**	Yes	Yes
IVT 2007	**In vitro diagnostic devices which require knowledge regarding the**	Yes	Yes
IVT 2008	**In vitro diagnostic devices manufactured in clean rooms and**	Yes	Yes
IVT 2009	**In vitro diagnostic devices manufactured using processing of materials of human, animal or micro- bial origin**	Yes	Yes
IVT 2010	**In vitro diagnostic devices manufactured using electronic components including communication de- vices**	Yes	Yes
IVT 2011	**In vitro diagnostic devices which require packaging, including labelling**	Yes	Yes
3. ***In vitro diagnostic devices which require specific knowledge in examination procedures for the purpose of product verification***			
IVP CODE	In vitro diagnostic devices which require specific knowledge in examination procedures		
IVP 3001	**In vitro diagnostic devices which require knowledge regarding agglutination tests**	Yes	Yes
IVP 3002	**In vitro diagnostic devices which require knowledge regarding biochemistry**	Yes	Yes
IVP 3003	**In vitro diagnostic devices which require knowledge regarding chromatography**	Yes	Yes
IVP 3004	**In vitro diagnostic devices which require knowledge regarding chromosomal analysis**	Yes	Yes
IVP 3005	**In vitro diagnostic devices which require knowledge regarding coagulometry**	Yes	Yes
IVP 3006	**In vitro diagnostic devices which require knowledge regarding flow cytometry**	Yes	Yes
IVP 3007	**In vitro diagnostic devices which require knowledge regarding immunoassays**	Yes	Yes
IVP 3008	**In vitro diagnostic devices which require knowledge regarding lysis based testing**	Yes	Yes
IVP 3009	**In vitro diagnostic devices which require knowledge regarding measurement of radioactivity**	Yes	Yes

IVP 3010	**In vitro diagnostic devices which require knowledge regarding microscopy**	Yes	Yes
IVP 3011	**In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)**	Yes	Yes
IVP 3012	**In vitro diagnostic devices which require knowledge regarding physical chemistry including electro- chemistry**	Yes	Yes
IVP CODE	In vitro diagnostic devices which require specific knowledge in examination procedures		
IVP 3013	**In vitro diagnostic devices which require knowledge regarding spectroscopy**	Yes	Yes
IVP 3014	**In vitro diagnostic devices which require knowledge regarding tests of cell function**	Yes	Yes
4. *In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification*			
IVD CODE	In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification		
IVD 4001	**In vitro diagnostic devices which require knowledge regarding bacteriology**	Yes	Yes
IVD 4002	**In vitro diagnostic devices which require knowledge regarding clinical chemistry/biochemistry**	Yes	Yes
IVD 4003	**In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)**	Yes	Yes
IVD 4004	**In vitro diagnostic devices which require knowledge regarding genetics**	Yes	Yes
IVD 4005	**In vitro diagnostic devices which require knowledge regarding haematology/haemostasis, including coagulation disorders**	Yes	Yes
IVD 4006	**In vitro diagnostic devices which require knowledge regarding histocompatibility and immunoge- netics**	Yes	Yes
IVD 4007	**In vitro diagnostic devices which require knowledge regarding immunohistochemistry/histology**	Yes	Yes
IVD 4008	**In vitro diagnostic devices which require knowledge regarding immunology**	Yes	Yes
IVD 4009	**In vitro diagnostic devices which require knowledge regarding molecular biology/diagnostics**	Yes	Yes
IVD 4010	**In vitro diagnostic devices which require knowledge regarding mycology**	–	Yes

IVD 4011	**In vitro diagnostic devices which require knowledge regarding parasitology**	Yes	Yes
IVD 4012	**In vitro diagnostic devices which require knowledge regarding virology**	Yes	Yes

MedTech Europe

Notified Bodies listed in NANDO under MDR and IVDR, including designation codes

Last updated on 30/10/2019

3	4
BSI NL NB 2797	**TÜV SÜD PS NB 0123**
24/12/2019	17/06/2020
Link to NANDO	Link to NANDO
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI

MedTech Europe

Notified Bodies listed in NANDO under MDR and IVDR, including designation codes

lated on 30/10/2019

Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI

MedTech Europe

Notified Bodies listed in NANDO under MDR and IVDR, including designation codes

Last updated on 30/10/2019

Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
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Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
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Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
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Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II)	Annex X Annex IX(I) Annex IX(II) Annex XI

MedTech Europe

Notified Bodies listed in NANDO under MDR and IVDR, including designation codes

lated on 30/10/2019

Annex IX(I) Annex IX(II) Annex XI	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II) Annex XI	Annex X Annex IX(I) Annex IX(II) Annex XI
Annex IX(I) Annex IX(II) Annex XI	Annex X Annex IX(I) Annex IX(II) Annex XI
Yes	Yes
Yes	Yes
Yes	Yes
Yes	Yes
Yes	including: aseptic processing; etylene oxide gas sterilisation (EOG); low temperature steam and formaldehyde sterilisation; moist heat sterilisation; radiation sterilisation (gamma, x-ray, electron beam);
Yes	Yes
Yes	Yes
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MedTech Europe
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Last updated on 30/10/2019