

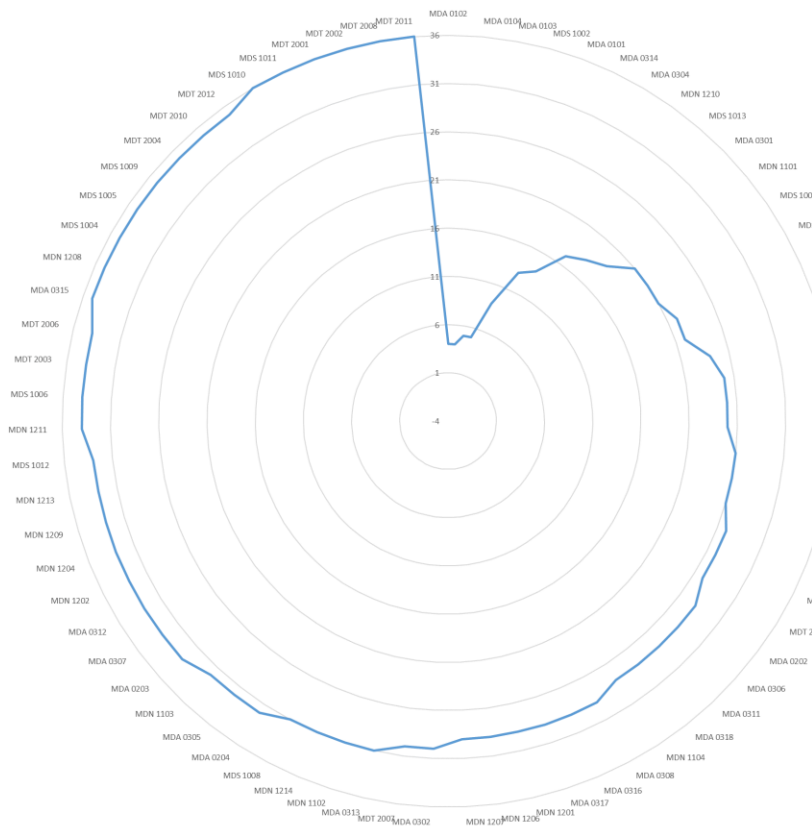


Coverage of designation codes by MDR/IVDR notified bodies

January 2023

Summary MDR codes coverage

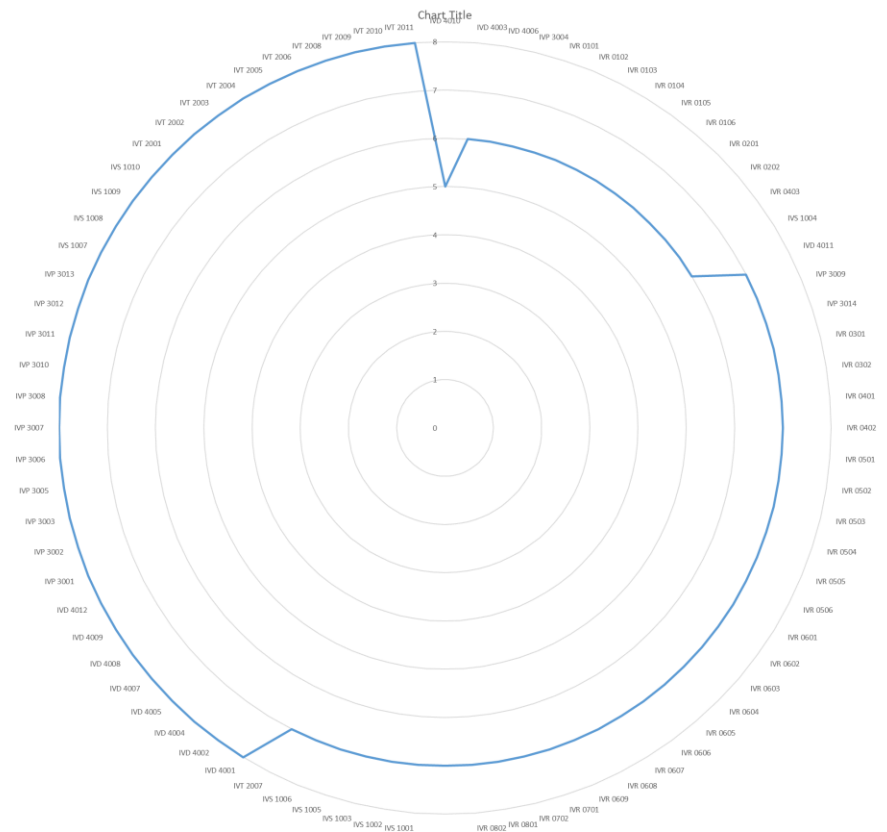
MDR CODES COVERAGE



- More than 80% of codes are covered by more than 20/36 NBs
- Just 5 codes are covered by less than 1/3 NBs:
 - MDA 0102: Active implantable devices delivering drugs or other substances
 - MDA 0104: Active implantable devices utilising radiation and other active implantable devices
 - MDA 0103: Active implantable devices supporting or replacing organ functions
 - MDA 0101: Active implantable devices for stimulation/inhibition/monitoring
 - MDS 1002: Devices manufactured utilising tissues or cells of human origin, or their derivatives

Summary IVDR codes coverage

IVDR CODES COVERAGE

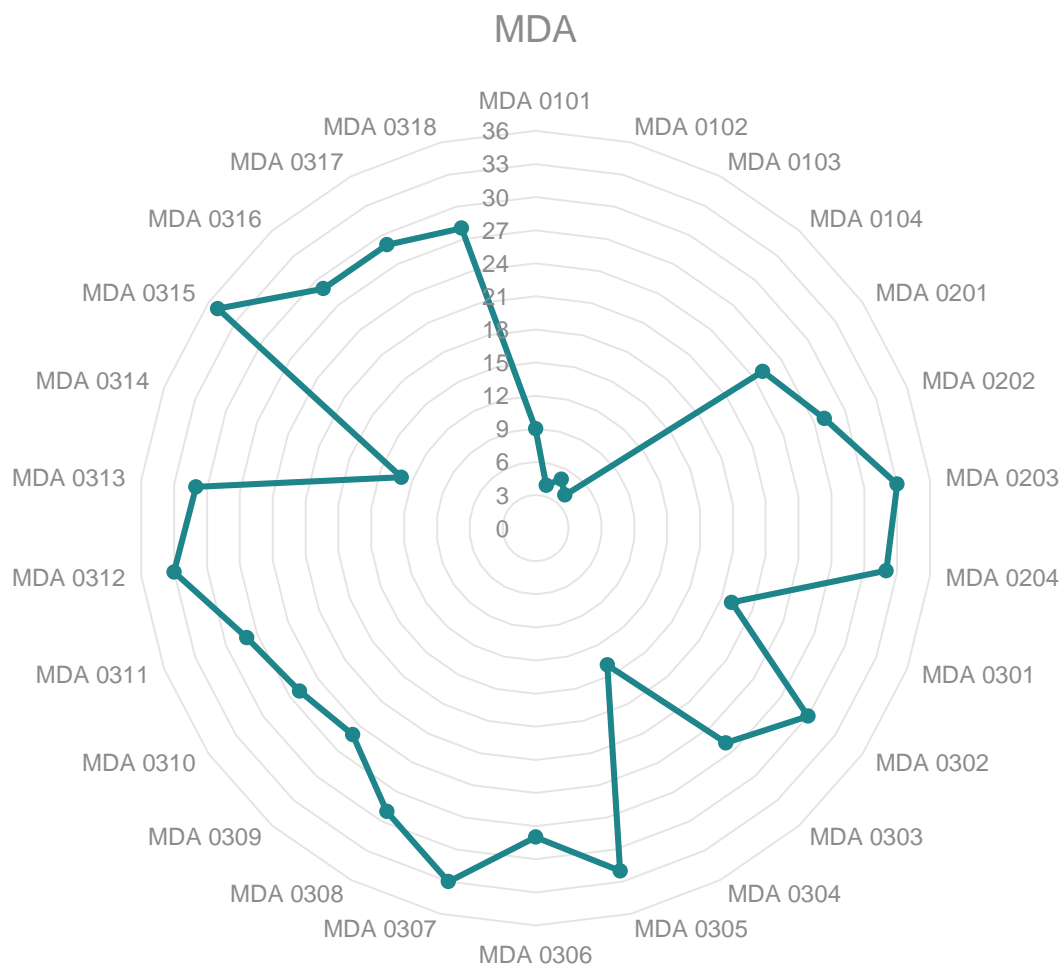


- Over 80% of codes are covered by 7/8 NBs;
- Only one code is covered by 5/8 NBs:
 - IVD 4010: In vitro diagnostic devices which require knowledge regarding mycology

Regulation (EU) 2017/745

**COVERAGE OF MDR CODES BY THE NOTIFIED
BODIES CURRENTLY DESIGNATED**

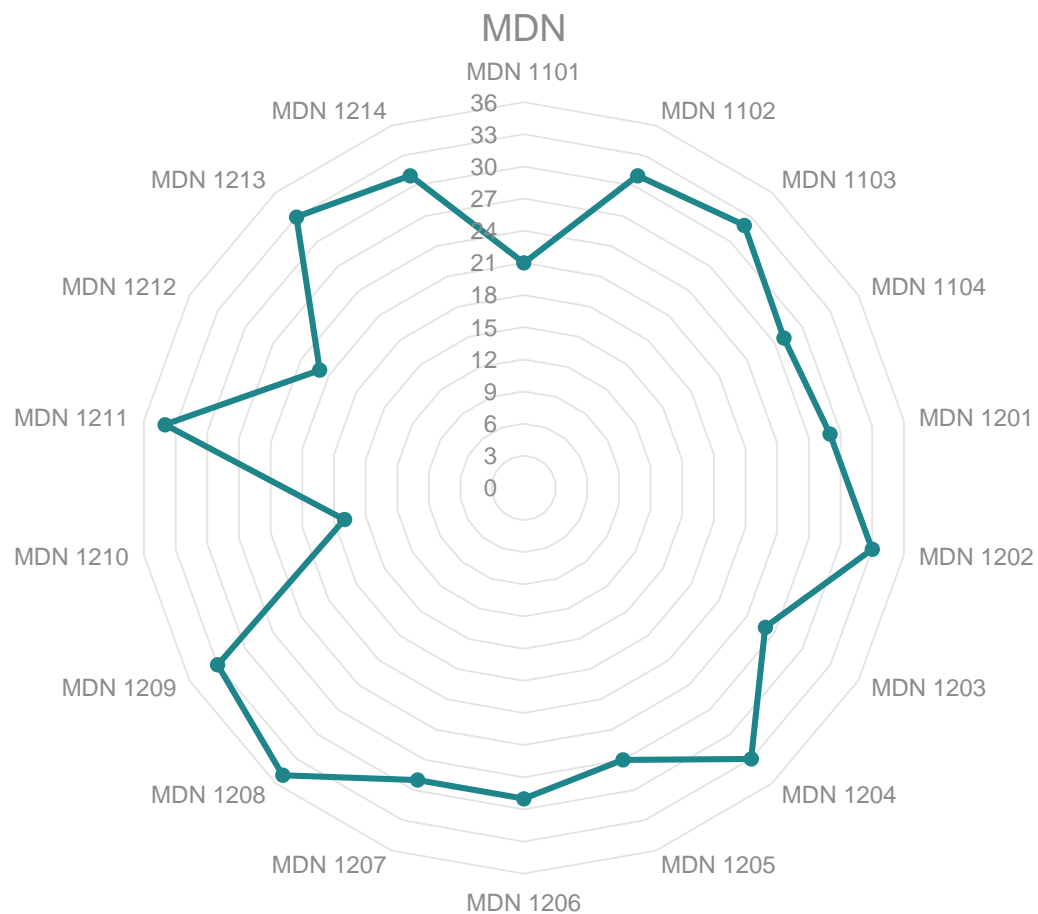
MDA



MDA CODE*	DESCRIPTION	N of NBs
MDA 0102	Active implantable devices delivering drugs or other substances	4
MDA 0104	Active implantable devices utilising radiation and other active implantable devices	4
MDA 0103	Active implantable devices supporting or replacing organ functions	5
MDA 0101	Active implantable devices for stimulation/inhibition/monitoring	9
MDA 0314	Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	13
MDA 0304	Active non-implantable devices for shock-wave therapy (lithotripsy)	14
MDA 0301	Active non-implantable devices utilising ionizing radiation	19

*MDA CODES are indicated in the table if the number of NBs is less than 20

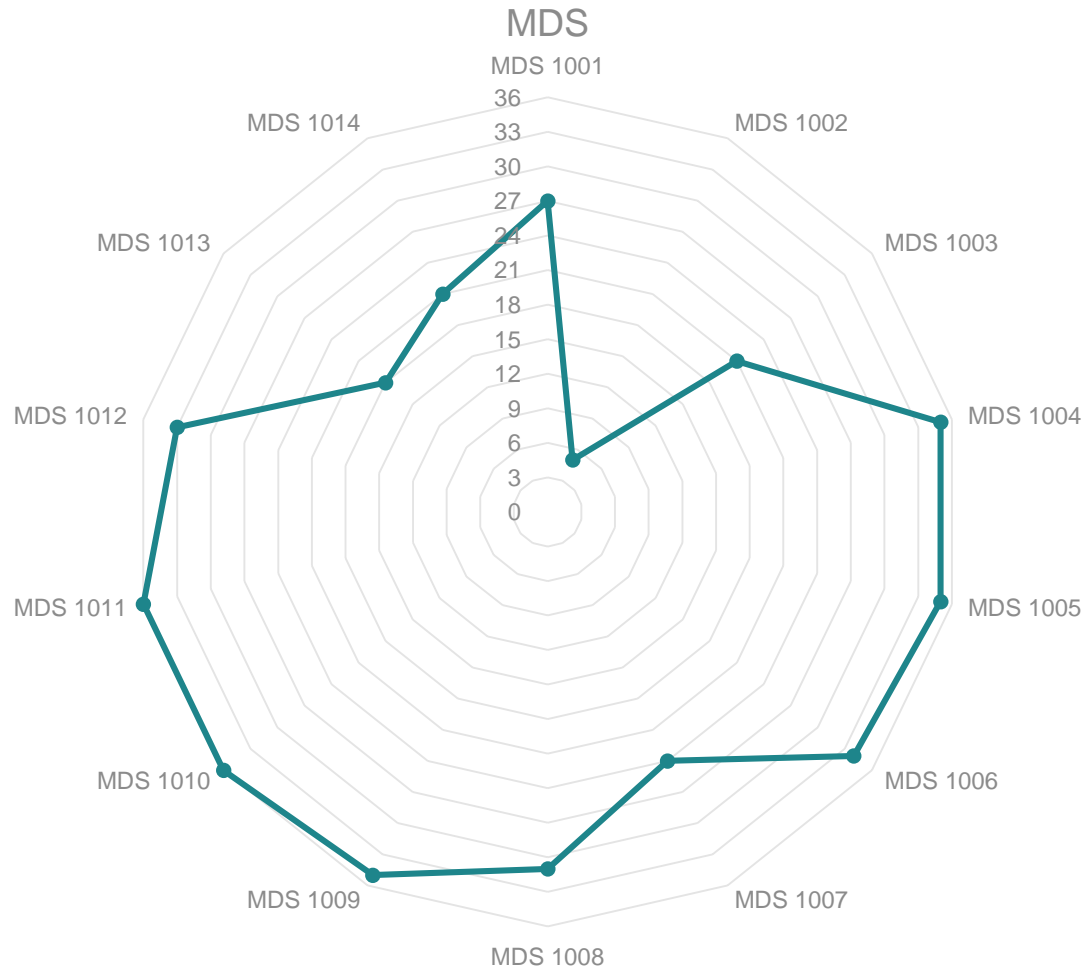
MDN



MDN CODE*	DESCRIPTION	N of NBs
MDN 1210	Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	17

*MDN CODES are indicated in the table if the number of NBs is less than 20

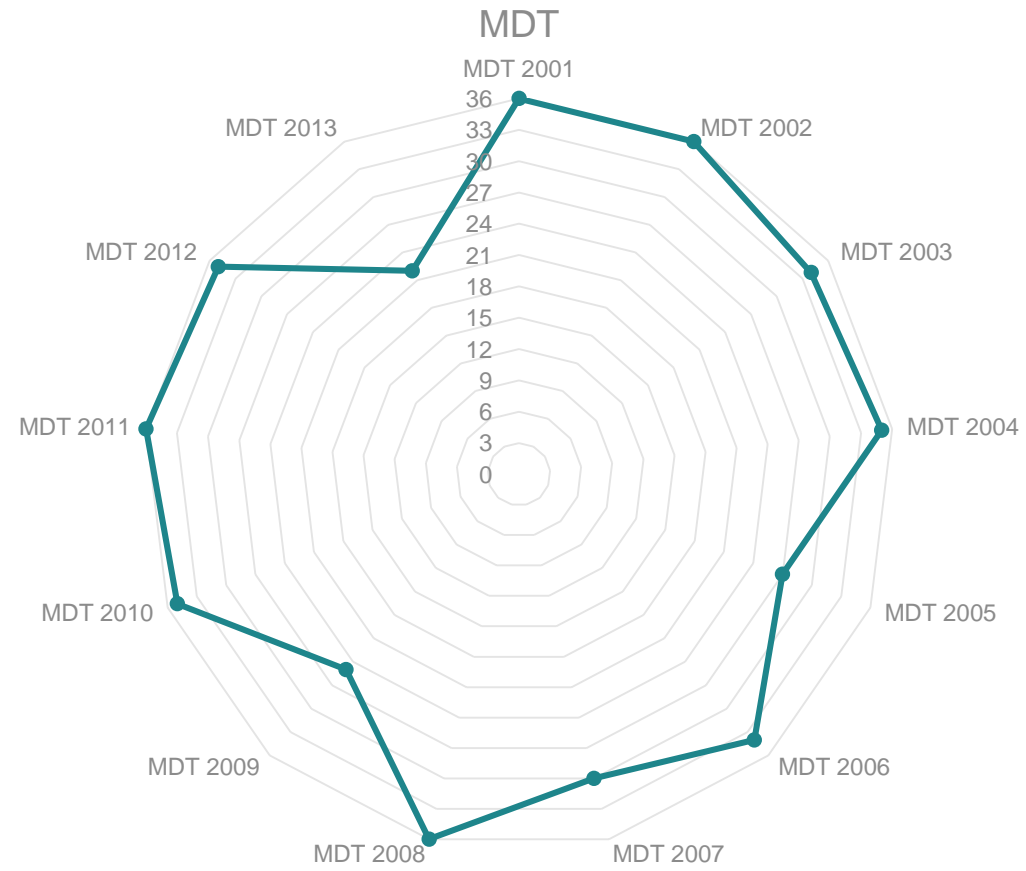
MDS



MDS CODE*	DESCRIPTION	N of NBs
MDS 1002	Devices manufactured utilising tissues or cells of human origin, or their derivatives	5
MDS 1013	Class III custom-made implantable devices	18

*MDS CODES are indicated in the table if the number of NBs is less than 20

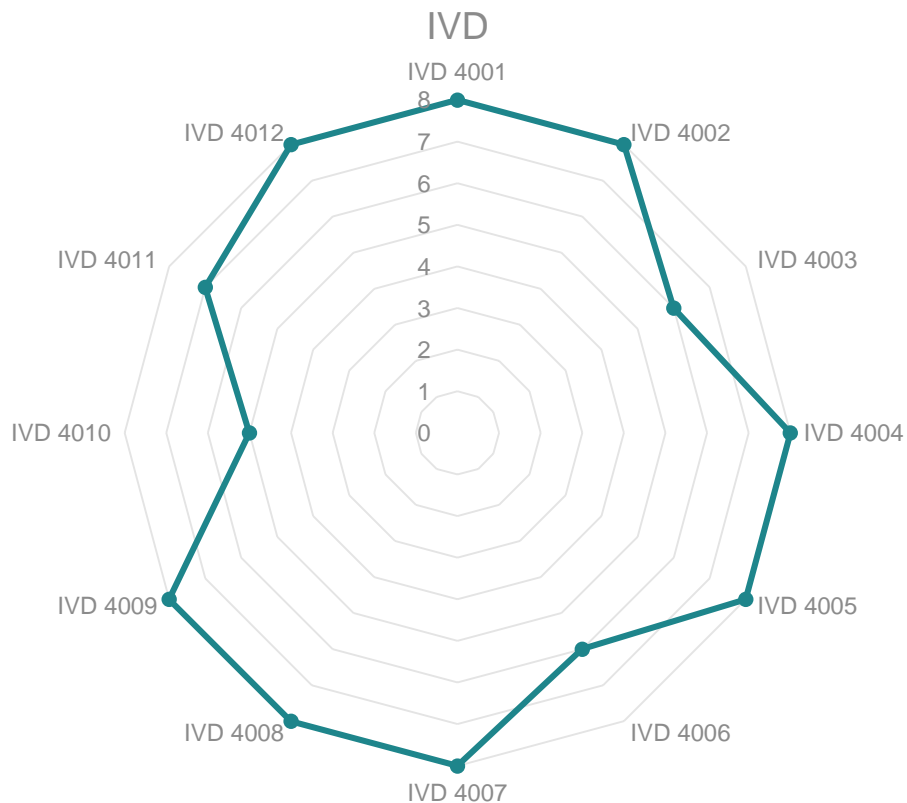
MDT



Regulation (EU) 2017/746

**COVERAGE OF IVDR CODES BY NOTIFIED
BODIES CURRENTLY DESIGNATED**

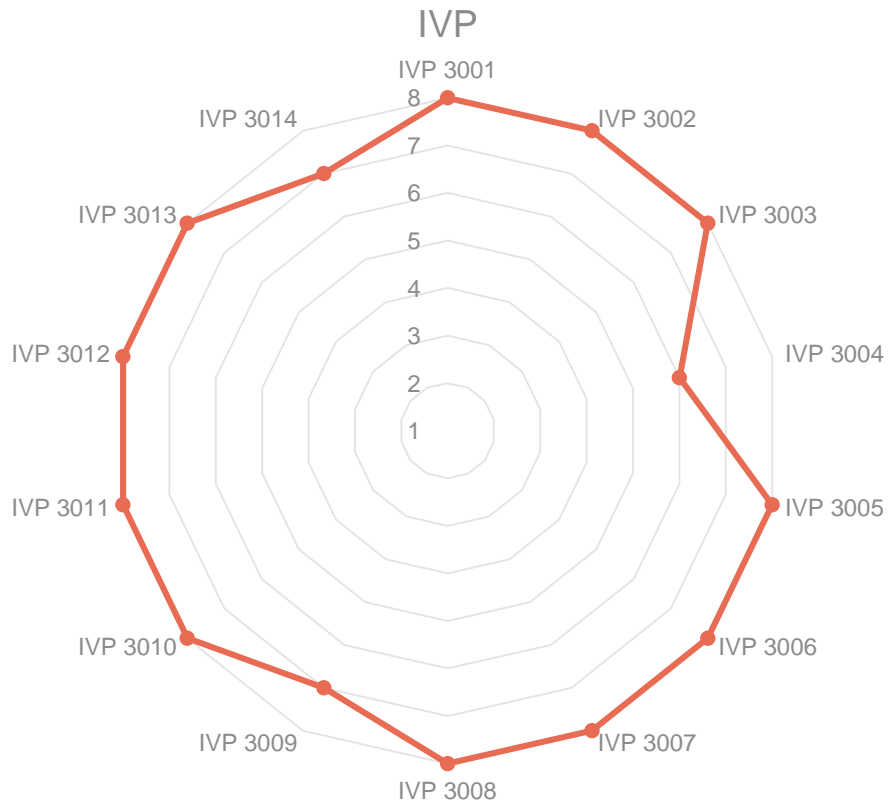
IVD



IVD CODE*	DESCRIPTION	N of NBs
IVD 4010	In vitro diagnostic devices which require knowledge regarding mycology	5
IVD 4003	In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)	6
IVD 4006	In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics	6

*IVD CODES are indicated in the table if the number of NBs is less than 7

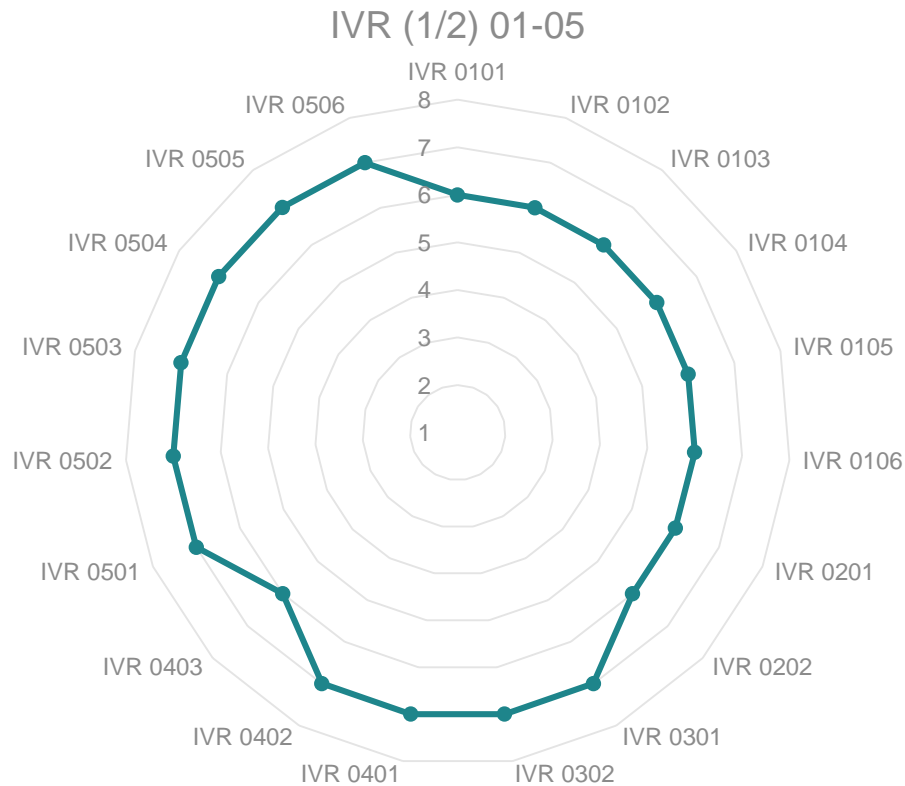
IVP



IVD CODE*	DESCRIPTION	N of NBs
IVP 3004	In vitro diagnostic devices which require knowledge regarding chromosomal	6

*IVP CODES are indicated in the table if the number of NBs is less than 7

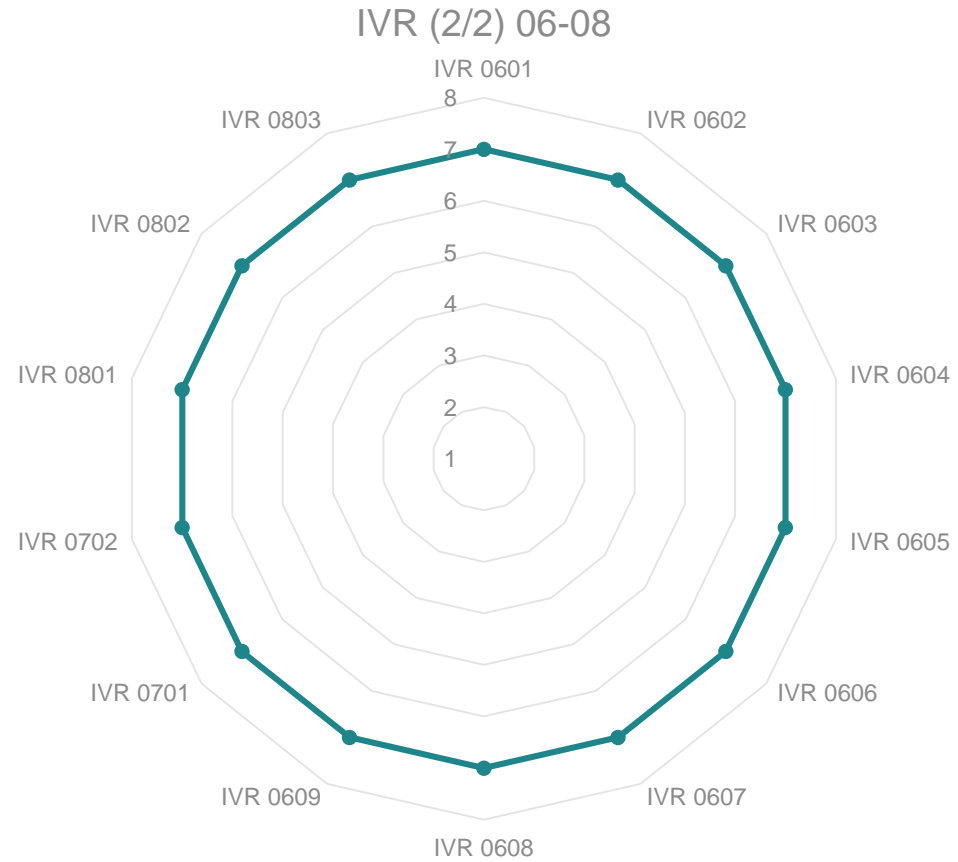
IVR (1/2)



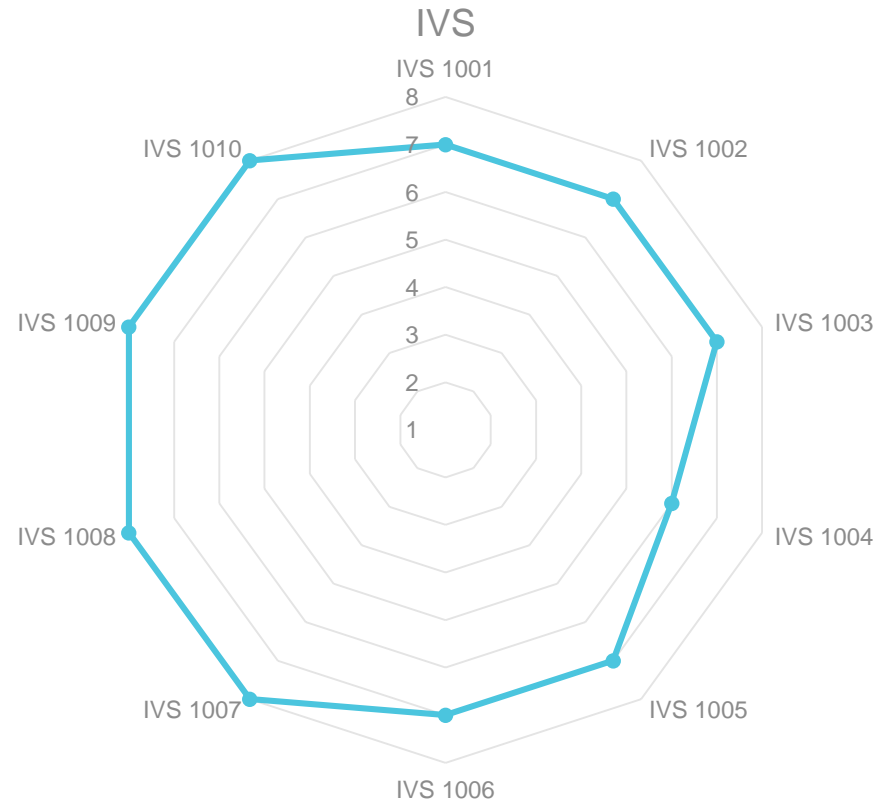
IVR CODE*	DESCRIPTION	N of NBs
IVR 0101	Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB]	6
IVR 0102	Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]	6
IVR 0103	Devices intended to determine markers of the Kell system [Ke1 (K)]	6
IVR 0104	Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]	6
IVR 0105	Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]	6
IVR 0106	Other devices intended to be used for blood grouping	6
IVR 0403	Other devices intended to be used for human genetic testing	6
IVR 0201	Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration	6
IVR 0202	Other devices intended to be used for tissue typing	6

*IVR CODES are indicated in the table if the number of NBs is less than 7

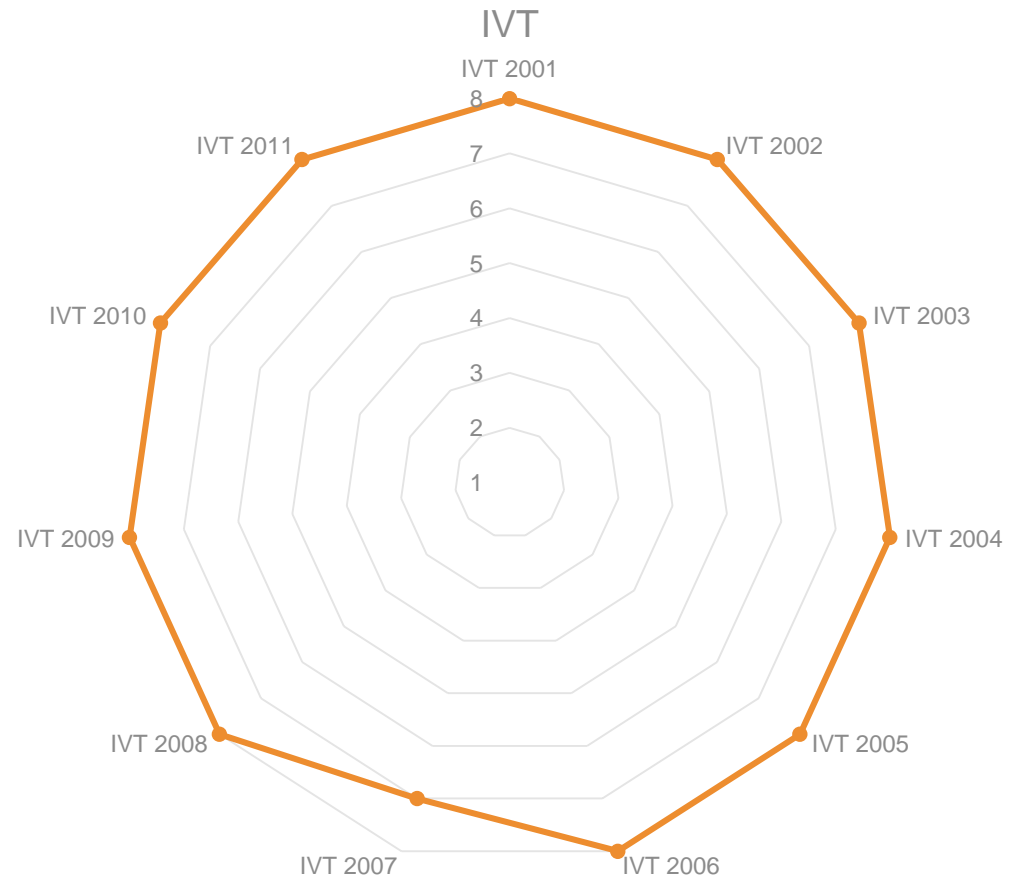
IVR (2/2)



IVS



IVS CODE	DESCRIPTION	N of NBs
IVS 1004	Devices manufactured utilising tissues or cells of human origin, or their derivatives	6





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