

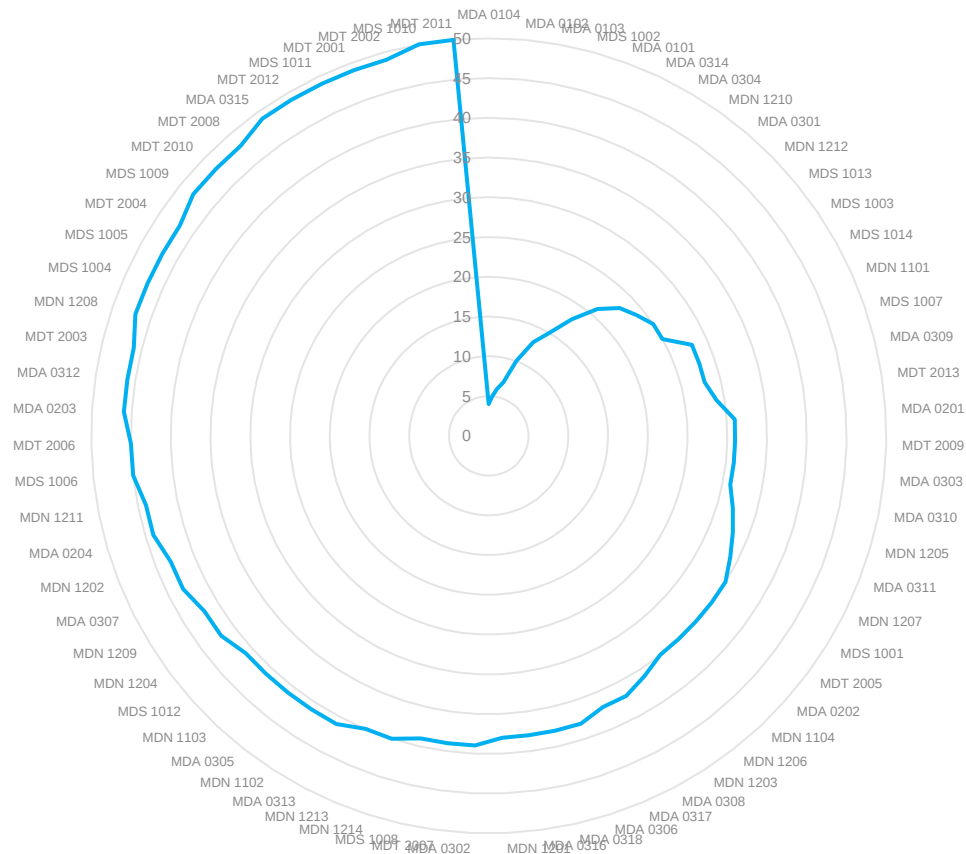


Coverage of designation codes by MDR/IVDR notified bodies

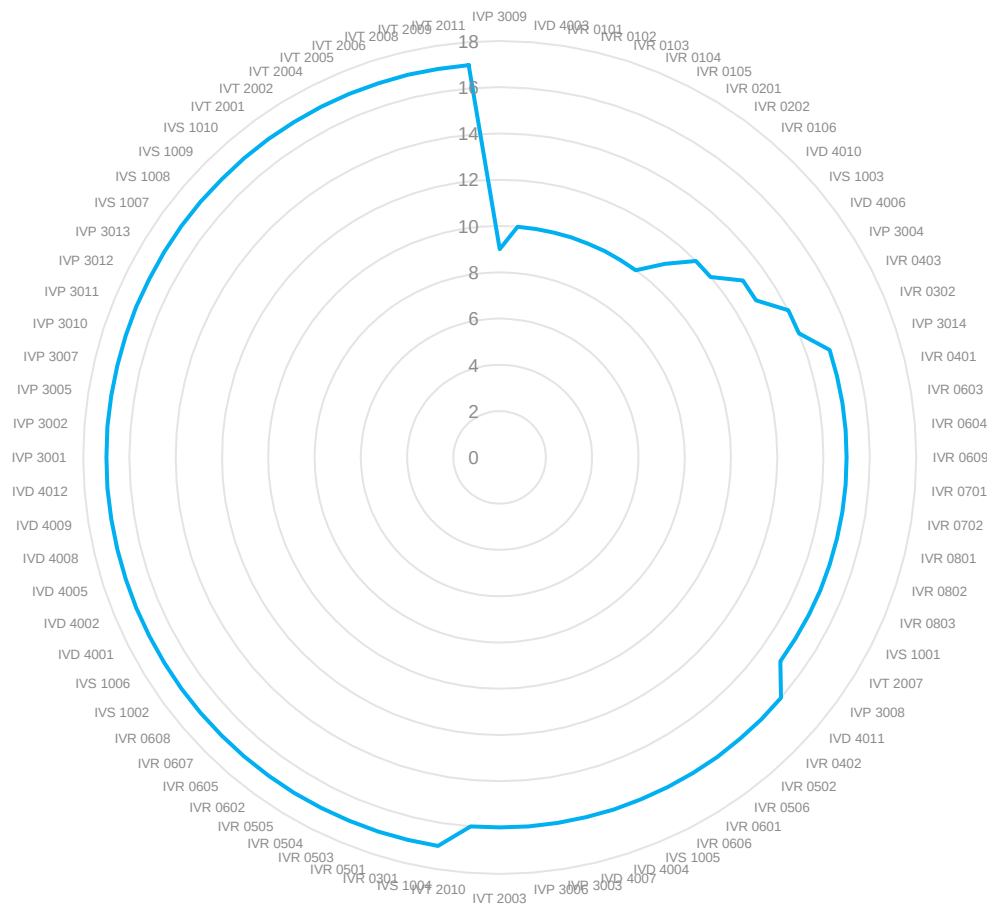
June 2025

Summary MDR codes coverage

MDR CODES COVERAGE



- 2/3 of the MDR codes that are covered by 35 or more NBs.
- Just 5 codes are covered by 10 or less 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

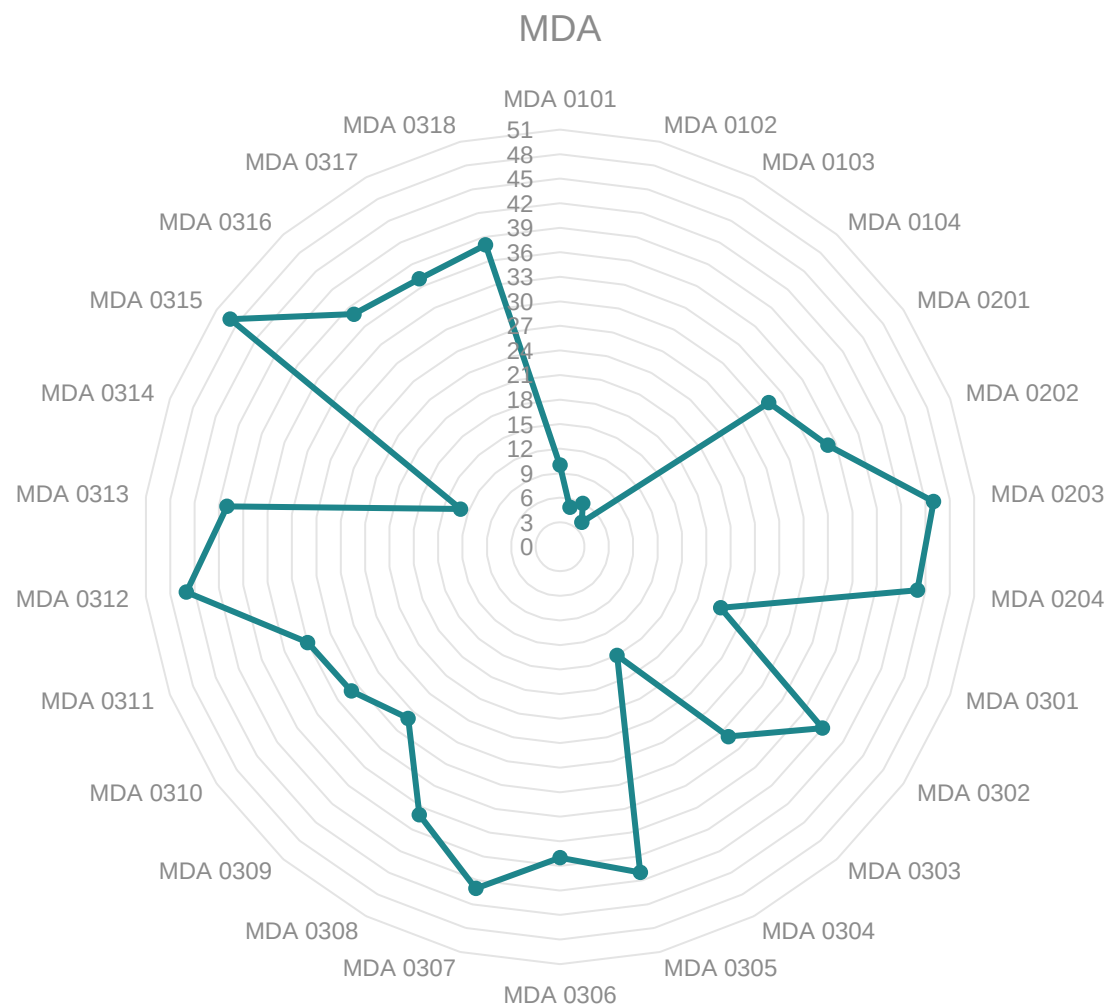


- Almost half of the codes (47,5%) of codes are covered by all of the 17 NBs
- 80% of codes are covered by 14 or more NBs;
- 9 codes are covered by 10 or less NBs:
 - IVR 0101 to IVR 0106 (blood grouping)
 - IVR 0201 and IVR 0202 (tissue typing)
 - IVP 3009: IVDs which require knowledge regarding measurement of radioactivity
 - IVD 4003: IVDs which require knowledge regarding detection of transmissible agents (without organisms or viruses)

Regulation (EU) 2017/745

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

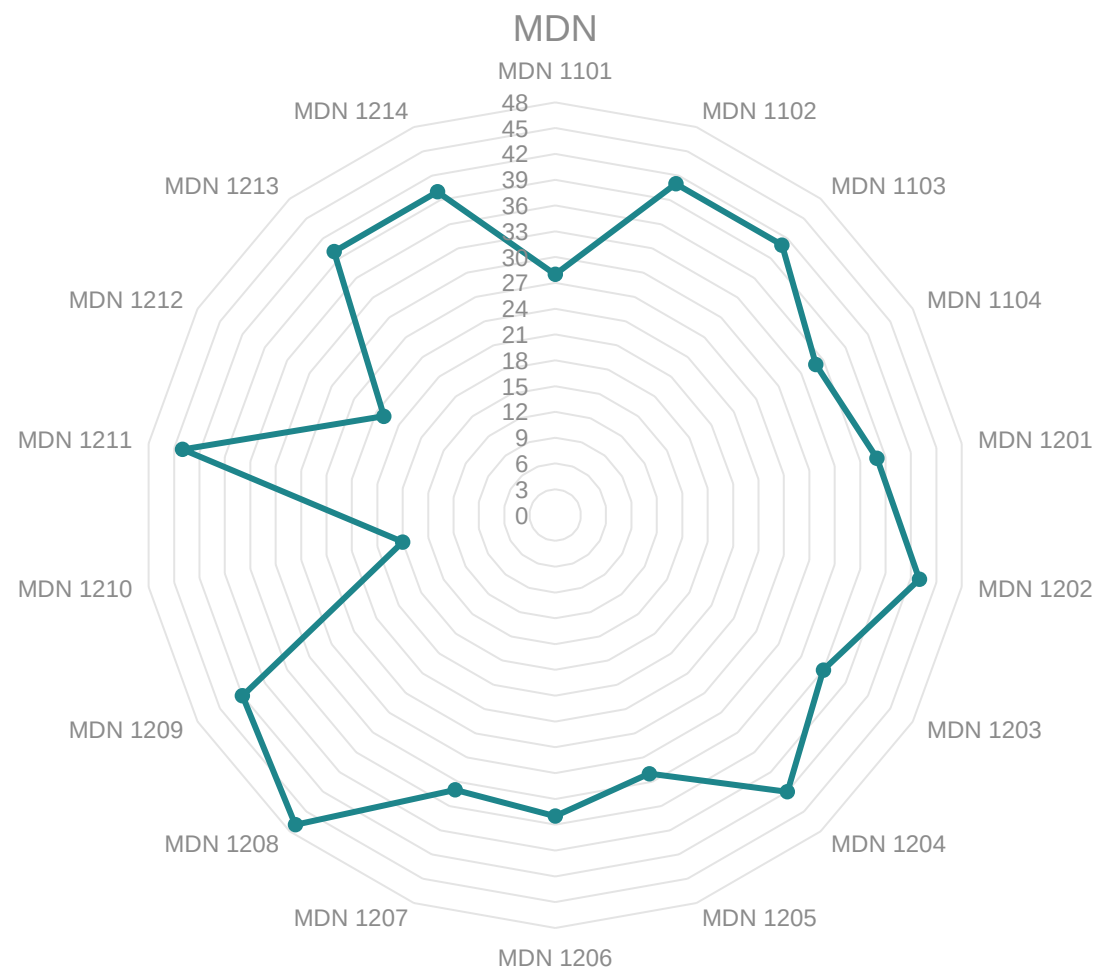
MDA



MDA CODE*	DESCRIPTION	N of NBs
MDA 0104	Active implantable devices utilising radiation and other active implantable devices	4
MDA 0102	Active implantable devices delivering drugs or other substances	5
MDA 0103	Active implantable devices supporting or replacing organ functions	6
MDA 0101	Active implantable devices for stimulation/inhibition/monitoring	10
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)	15

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

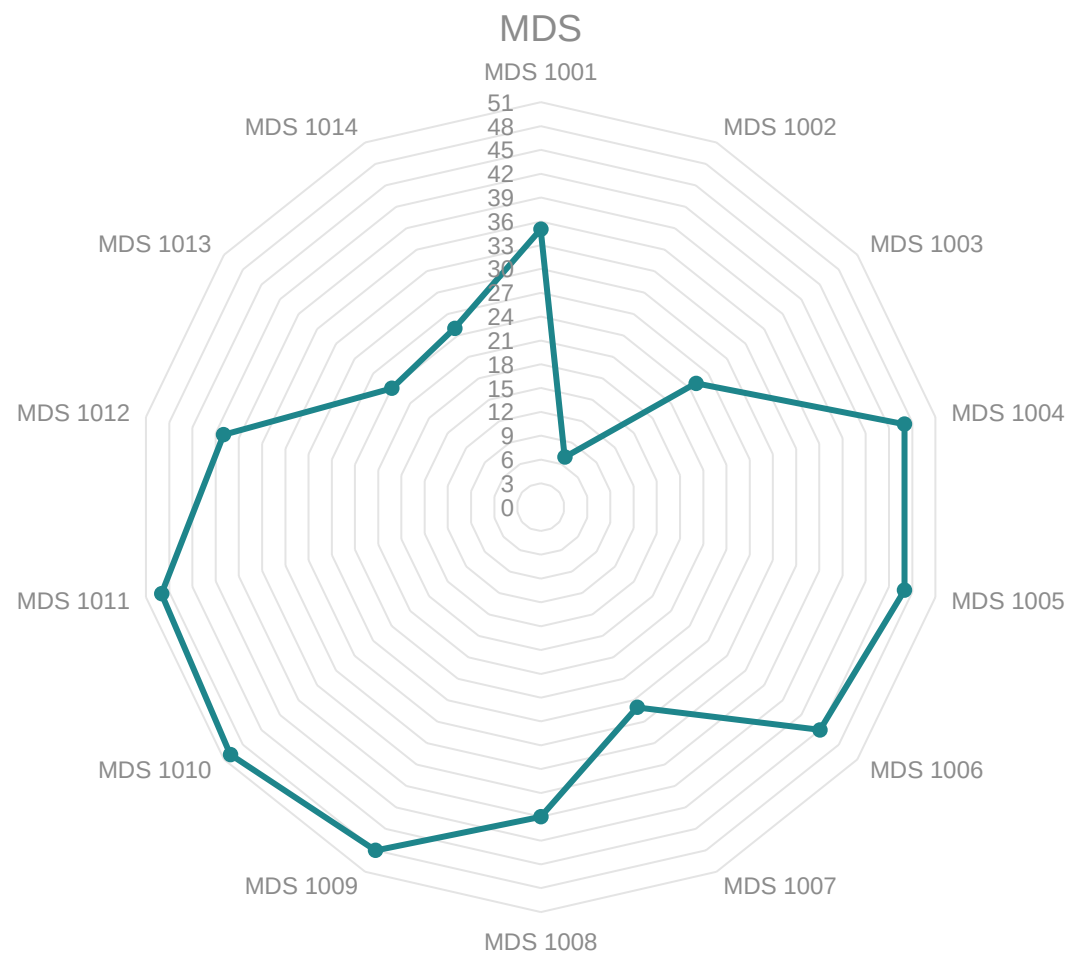
MDN



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	18

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

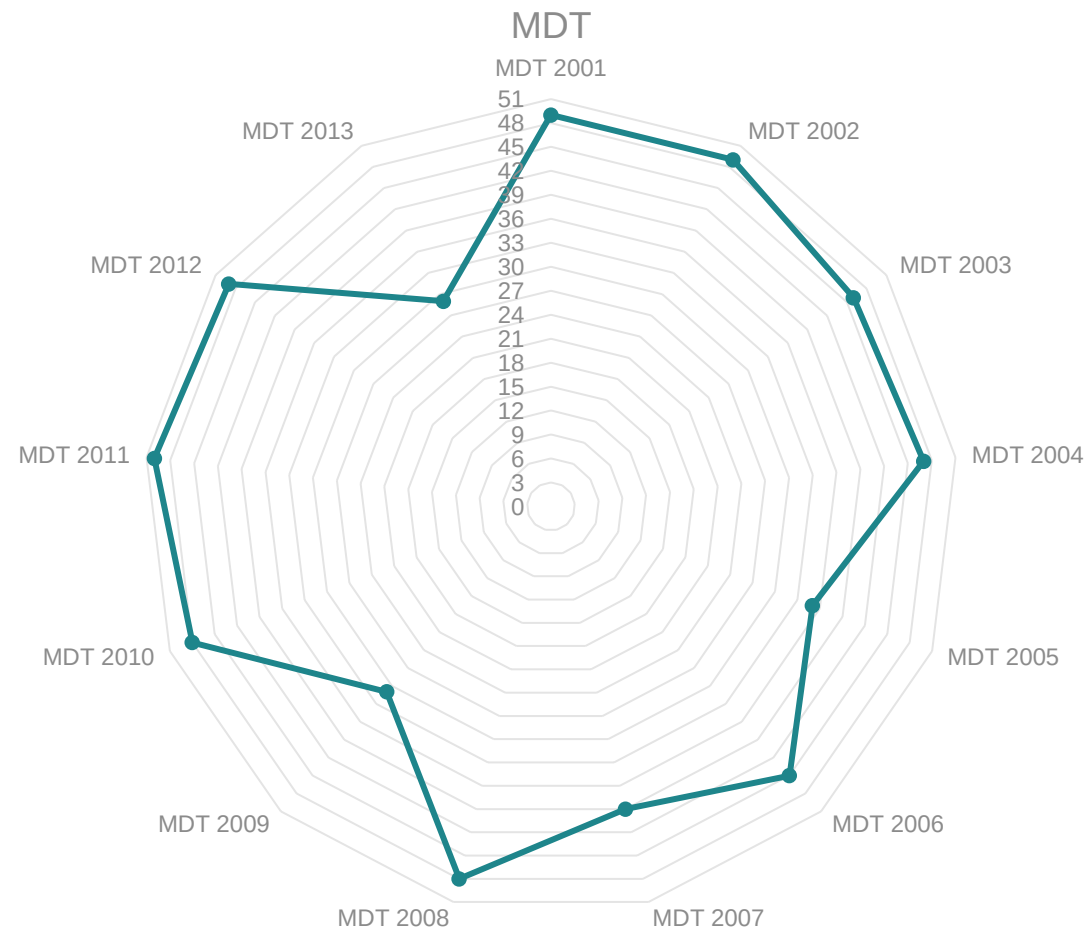
MDS



MDS CODE*	DESCRIPTION	N of NBs
MDS 1002	Devices manufactured utilising tissues or cells of human origin, or their derivatives	7

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

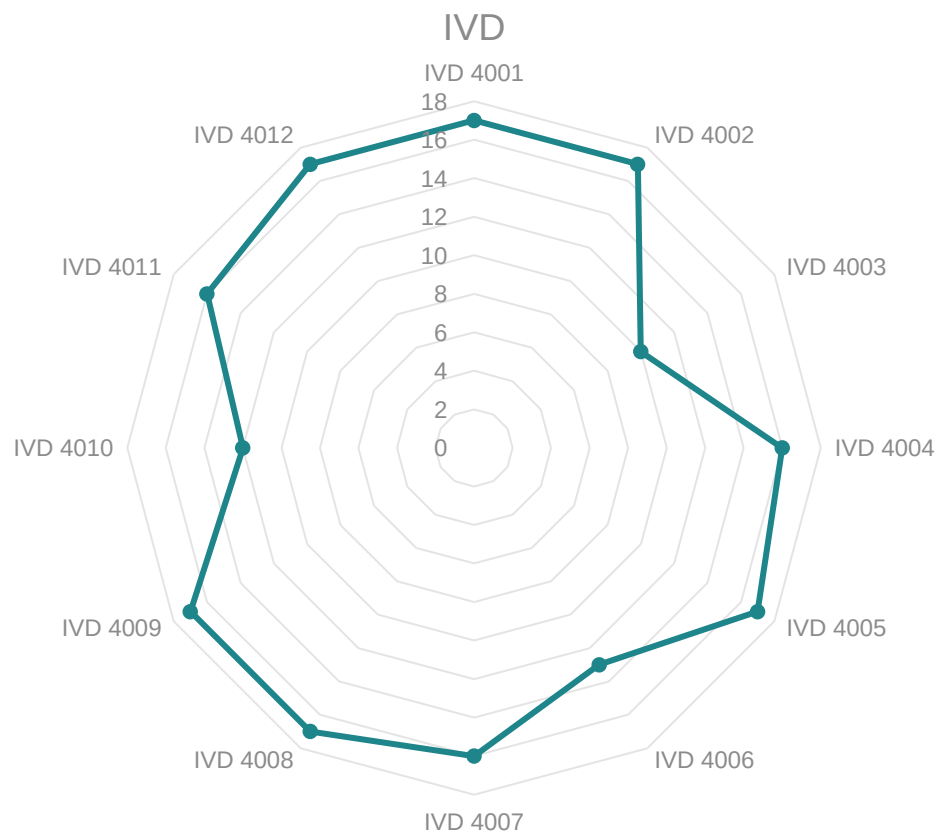
MDT



Regulation (EU) 2017/746

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

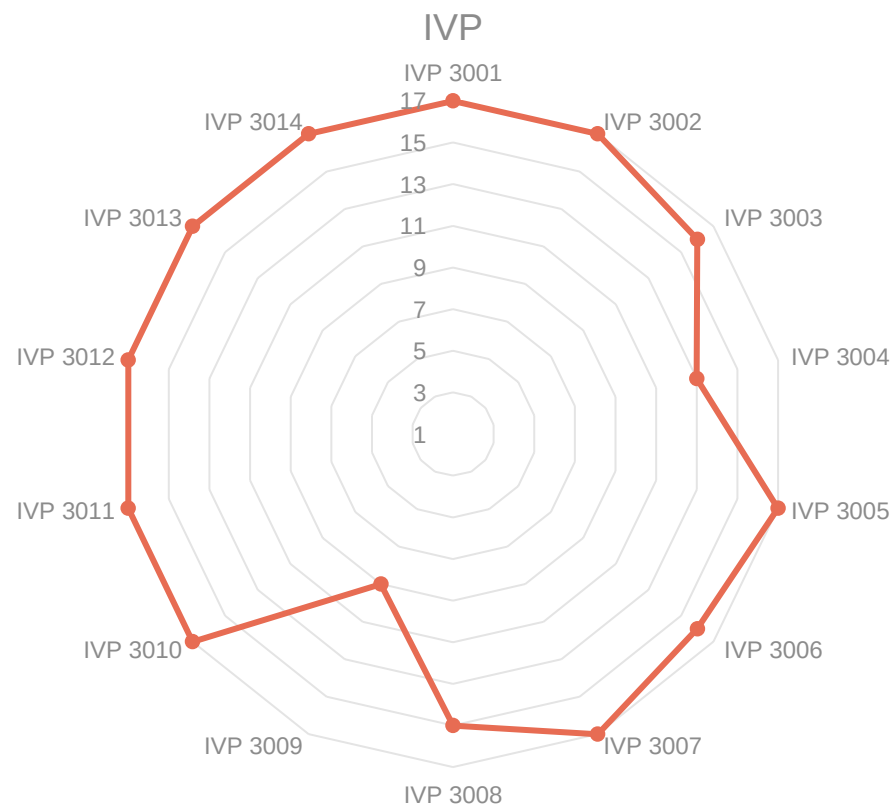
IVD



IVD CODE*	DESCRIPTION	N of NBs
IVD 4010	In vitro diagnostic devices which require knowledge regarding mycology	12
IVD 4003	In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)	10
IVD 4006	In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics	13

*IVD CODES are indicated in the table if the number of NBs is equal or less than 13

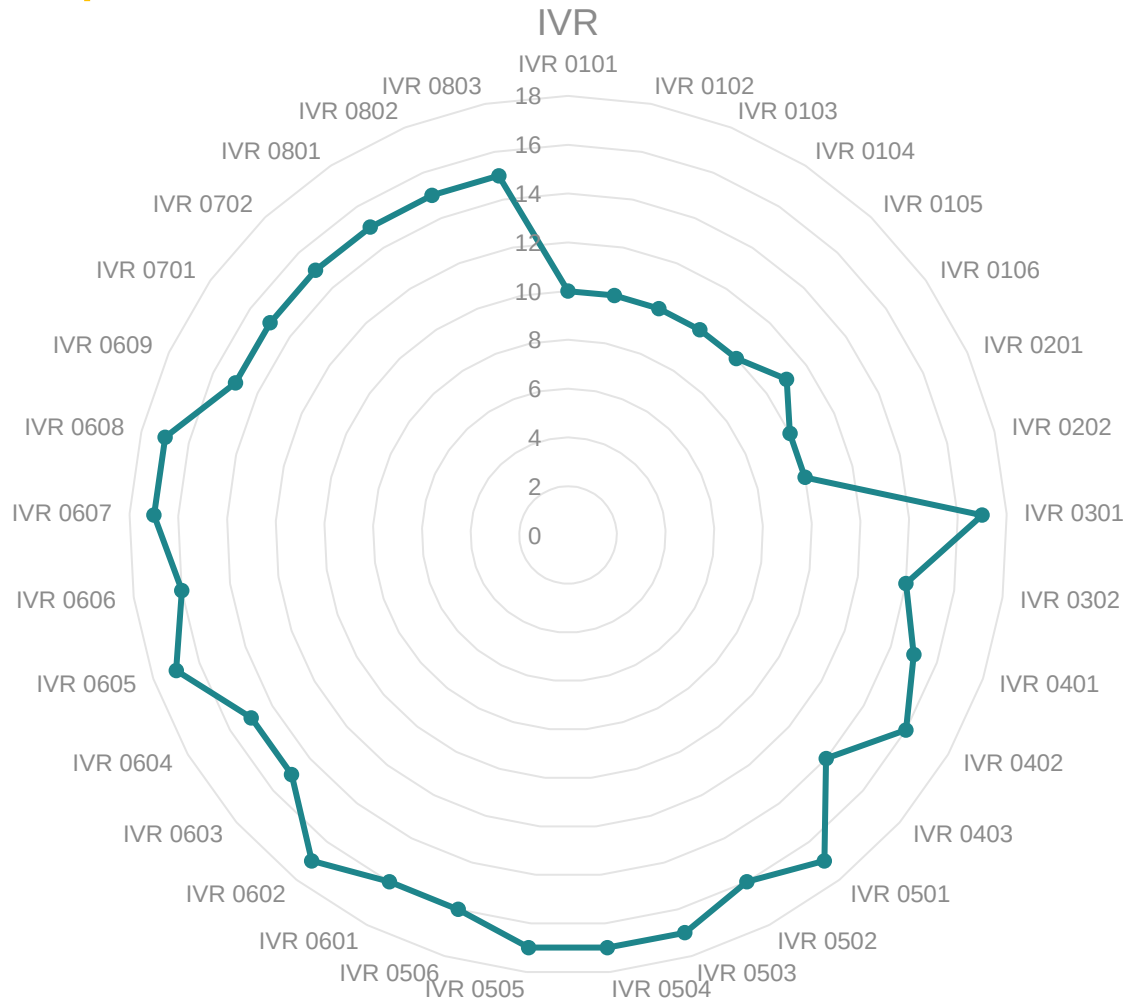
IVP



IVD CODE*	DESCRIPTION	N of NBs
IVP 3004	In vitro diagnostic devices which require knowledge regarding chromosomal	13
IVP 3009	In vitro diagnostic devices which require knowledge regarding measurement of radioactivity	9

*IVP CODES are indicated in the table if the number of NBs is equal or less than 13

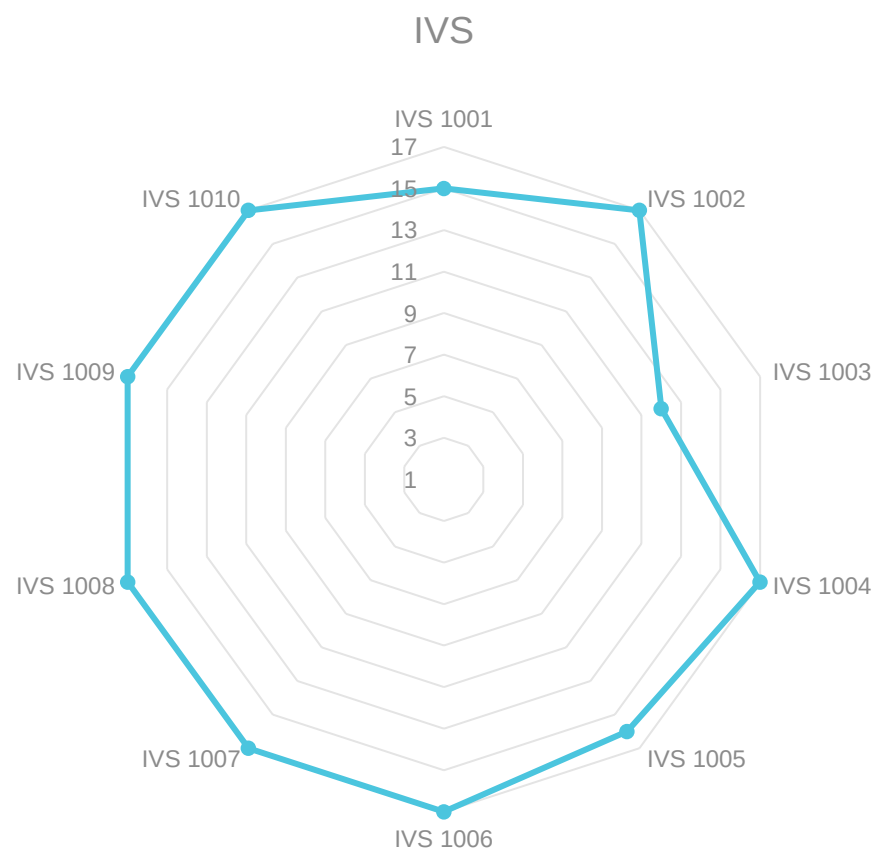
IVR



IVR CODE*	DESCRIPTION	N of NBs
IVR 0101	Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB]	10
IVR 0102	Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]	10
IVR 0103	Devices intended to determine markers of the Kell system [Kel1 (K)]	10
IVR 0104	Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]	10
IVR 0105	Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]	10
IVR 0106	Other devices intended to be used for blood grouping	11
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	10
IVR 0202	Other devices intended to be used for tissue typing	10

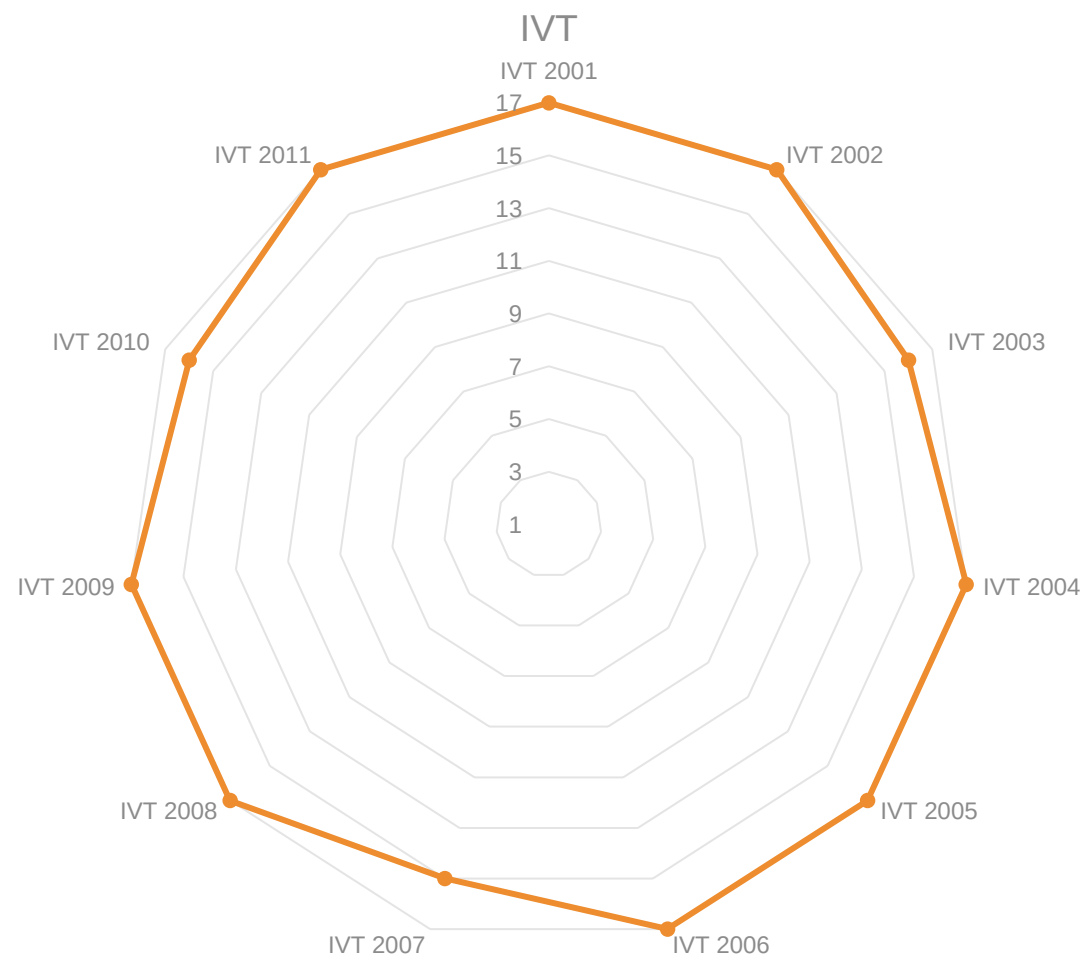
*IVR CODES are indicated in the table if the number of NBs is equal or less than 13

IVS



IVS CODE	DESCRIPTION	N of NBs
IVS 1003	Devices intended to be used as companion diagnostics	12

*IVP CODES are indicated in the table if the number of NBs is equal or less than 13





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