

Contact Points of National Authorities



België / Belgique / Belgien / Belgium

MDR - IVDR

FAMHP - Federal Agency for Medicines and Health Products

Avenue Galilée - Galileelaan 5/03, 1210 Brussels, fax:+32 2 528 4120

E-mail: welcome@fagg-afmps.be

[Web site](#)



България / Bulgaria

MDR – IVDR

Bulgarian Drug Agency

8 Damyan Gruev Str., BG - 1303 Sofia,

E-mail: bda@bda.bg

[Web site](#)



Ceska Republika / Czech Republic

MDR - IVDR

State Institute for Drug Control, Medical Devices Section

Šrobárova 48, CZ – 100 41 Prague 10,

E-mail: urgent@sukl.cz

[Web site](#)



Hrvatska / Croatia

MDR - IVDR

Agency for Medicinal Products and Medical Devices

Ksaverska cesta 4, 10 000 Zagreb,

E-mail: -

[Web site](#)

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Danmark / Denmark

MDR - IVDR

Danish Medicines Agency

Pharmacovigilance and Medical Devices
Axel Heides Gade 1, DK - 2300 - Kobenhavn,
E-mail: med-udstyr@dkma.dk

[Web site](#)



Deutschland / Germany

MDR-IVDR Legislation

Federal Ministry of Health

Friedrichstr. 108 - 10117 Berlin, fax:+ 49 228 941-4946
E-mail: medizinprodukte@bmg.bund.de

[Web site](#)

Authority responsible for notified bodies

**Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
(ZLG)**

Heinrich-Böll-Ring 10, 53119 Bonn,
E-mail: zlg@zlg.nrw.de

[Web site](#)

MDR-IVDR

Federal Institute for Drugs and Medical Devices

Kurt Georg Kiesinger Allee 3, D - 53175 Bonn,
E-mail: medizinprodukte@bfarm.de

[Web site](#)

IVDR

Paul Ehrlich Institute, Section Pharmacovigilance 2

Paul-Ehrlich-Strasse 51-59, D - 63225 Langen,
E-mail: pharmacovigilance2@pei.de

[Website](#)

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Eesti / Estonia

MDR-IVDR

State Agency of Medicines

Nooruse 1, EE - Tartu 50411

E-mail: MSO@ravimiamet.ee

[Web site](#)



Eire / Ireland

MDR-IVDR

Health Products Regulatory Authority

Kevin O'Malley House, Medical Devices Department,
Earlsfort Centre, Earlsfort Terrace, IE - Dublin D02 XP77

E-mail: devices@hpra.ie

[Web site](#)



Ellada / Greece

MDR-IVDR

National Organization for Medicines,

284 Mesogion Ave, GR- 15562 Holargos, Athens,

E-mail: vigilancematerial@eof.gr

[Web site](#)



España / Spain

MDR-IVDR

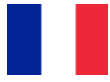
Agencia Española de Medicamentos y Productos Sanitarios

C/ Campezo 1, Edificio 8, ES - 28022 Madrid

E-mail: sgps@aemps.es

[Web site](#)

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France

MDR-IVDR

Agence Nationale de Sécurité du Médicament et des Produits de Santé

ANSM

143-147 boulevard Anatole France, FR - 93285 Saint Denis Cedex

E-mail: medicaldevicesvigilance@ansm.sante.fr

[Web site](#)



Italia / Italy

MDR-IVDR

Ministry of Health

Directorate General of Medical Devices and Pharmaceutical Services

via Giorgio Ribotta 5, IT - 00144 Roma,

E-mail: segr.dgfdm@sanita.it

[Website](#)



Kypros / Kibris / Cyprus

MDR-IVDR

Cyprus Medical Devices Competent Authority

Prodromou 1 & Chilonos 17 Corner, CY - 1449 Nicosia,

E-mail: cymda@mphs.moh.gov.cy

[Website](#)



Latvija / Latvia

MDR-IVDR

Medical Device Evaluation Department

State Agency of Medicines

15 Jersikas street, LV - 1003 Riga

E-mail: info@zva.gov.lv

[Website](#)

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Lietuva / Lithuania

MDR-IVDR

The State Health Care Accreditation Agency
under the **Ministry of Health of the Republic of Lithuania**
Jeruzales str. 21, LT-08420 Vilnius
E-mail: vaspvt@vaspvt.gov.lt
[Web site](#)



Luxembourg

MDR-IVDR

Ministry of Health
1, rue Charles Darwin
L-1433 Luxembourg
E-mail : meddevices@ms.etat.lu
Web site : <https://sante.public.lu/fr.html>



Malta

MDR-IVDR

Malta Medicines Authority - Medical Devices Unit
Sir Temi Żammit Buildings, Malta Life Sciences Park
San Ġwann SĠN 3000, Malta
E-mail : devices.medicinesauthority@gov.mt
[Web site](#)



Magyarország / Hungary

MDR-IVDR

National Institute of Pharmacy and Nutrition
1051, Budapest, Zrínyi street 3, Hungary
E-mail: amd.vig@ogyei.gov.hu
[Webpage](#)



Nederland / Netherlands

Notification & Registration

Ministry of Health, Welfare and Sports

CIBG Farmatec

Postal address: PO box 16114, NL - 2500 BC The Hague,

Visitors address: Rijnstraat 50, NL – 2515 XP Den Haag

E-mail: medische_hulpmiddelen@minvws.nl

[Web site](#)

Market Surveillance & Vigilance

Dutch Health and Youth Care Inspectorate (IGJ)

Visitor's address: Stadsplateau 1, 3521 AZ Utrecht,

Postal address: Postbus 2518, 6401 DA Heerlen

E-mail: meldpunt@igj.nl

[Web site](#)

Notification of clinical investigations (MDR) and performance studies (IVDR)

Central Committee on Research Involving Human Subjects (CCMO)

Postal address: P.O. Box 16302, 2500 BH Den Haag

E-mail: devices@ccmo.nl

[Web site](#)



Österreich / Austria

MDR-IVDR

Federal Ministry of Social Affairs, Health Care and Consumer Protection

Dept. Pharmaceuticals and Medical Devices

Radetzkystrasse 2, 1030 Wien/Vienna

E-mail: meddev@bmgf.gv.at

[Web site](#)

MDR-IVDR

Austrian Federal Office for Safety in Health Care (BASG)

Traisengasse 5, 1200 Wien

E-mail: medizinprodukte@basg.gv.at

[Web site](#)

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Polska / Poland

MDR-IVDR

Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, 02-222 Warsaw

E-mail: incydenty@urpl.gov.pl

[Web site](#)



Portugal

MDR-IVDR

Infarmed - National Authority of Medicines and Health Products

Parque da Saúde de Lisboa, Av. do Brasil, nº 53, PT - 1749-004 Lisboa

E-mail: daps@infarmed.pt

[Web site](#)



Romania

MDR-IVDR

National Agency for Medicines and Medical Devices of Romania

58, Sos. Nicolae Titulescu, sector 1, Bucharest

E-mail: drsp@anm.ro ; dgdm@anm.ro

[Web site](#)



Slovenija / Slovenia

MDR-IVDR

Agency for Medicinal Products and Medical Devices of the Republic of Slovenia JAZMP

Slovenčeva ulica 22, 1000 Ljubljana

E-mail: meddev@jazmp.si

[Web site](#)

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Slovenska Republika / Slovakia

MDR-IVDR

State Institute for Drug Control, Medical Devices Section

Kvetna 11, SK - 825 08 Bratislava

E-mail: sukl@sukl.sk

[Web site](#)



Suomi / Finland

MDR-IVDR

Finnish Medicines Agency Fimea

Medical Devices Unit

Mannerheimintie 166, P.O. Box 55, FI-00034 FIMEA

Email: medicaldevice@fimea.fi, registry@fimea.fi

[Web site](#)



Sverige / Sweden

MDR-IVDR

Swedish Medical Products Agency 'Läkemedelsverket'

Department of Medical Devices

Box 26, SE-751 03 Uppsala,

E-mail: registrator@lakemedelsverket.se

[Web site](#)



Norway / Norge

MDR-IVDR

Statens legemiddelverk/ Norwegian Medicines Agency

Norwegian Medical Products Agency, NoMA

PO Box 240 Skøyen, N-0213 Oslo, tel: +47 22 89 77 00

E-mail: MSOD@noma.no

[Web site](#)

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Iceland / Island

MDR-IVDR

Icelandic Medicines Agency

Vínlandsleið 14, IS-113 Reykjavík

E-mail: ima@ima.is

[Web site](#)



Liechtenstein

MDR-IVDR

Office of Public Health

Äulestrasse 51, Postfach 684, FL - 9490 Vaduz

E-mail: medical.devices@llv.li

[Web site](#)



Türkiye

MDR-IVDR

Turkish Medicines and Medical Devices Agency (TITCK)

Ministry of Health

Turkish Medicines and Medical Devices Agency

Söğütözü Mahallesi 2176. Sokak No:5 P.K. 06520 Çankaya Ankara

E-mail: md.reg@titck.gov.tr

[Web site](#)