

Performance study contact points



België / Belgique / Belgien / Belgium

MDR - IVD MR

FAMHP - Federal Agency for Medicines and Health Products

Avenue Galilée - Galileelaan 5/03, 1210 Brussels, tel: +32 2 528 4000

E-mail: ct.rd@fagg-afmps.be



Bulgaria

Head of Division 'Medical devices': **Todor Darakchiev**

Bulgarian Drug Agency

8 Damyan Gruev Str., BG - 1303 Sofia, tel:+359 2 890 34 83, fax:+359 2 890 34 34

E-mail: todor.darakchiev@bda.bg, bda@bda.bg - [Web site](#)



Ceska Republika / Czech Republic

State Institute for Drug Control

Department of Clinical Evaluation of Medical Devices and Vigilance

Medical Devices Section

Šrobárova 48, 100 41 Prague 10

E-mail: khv@sukl.cz



Hrvatska / Croatia

Romana Katalinić - tel: +385 1 4607 541

Ministry of Health of the Republic of Croatia

Ksaver 200a, 10000 Zagreb

E-mail: romana.katalinic@miz.hr – [Web site](#)



Danmark / Denmark

Danish Medicines Agency

Axel Heides Gade 1, DK - 2300 - Kobenhavn

E-mail: med-udstyr@dkma.dk



Deutschland / Germany

Ulf Schriever - tel:+49 228 207 4137, fax:+49 228 207 5300

Federal Institute for Drugs and Medical Devices

Kurt Georg Kiesinger Allee 3, D - 53175 Bonn

E-mail: medizinprodukte@bfarm.de



Eesti / Estonia

**State Agency of Medicines,
Medical Devices Department**

Nooruse 1., EE - Tartu 50411

E-mail: mso@ravimiamet.ee

Web site: <https://ravimiamet.ee/en>



Ireland / Eire

Health Products Regulatory Authority

Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IE - Dublin 2

E-mail: devices@hpra.ie - [Web site](#)



Ellada / Greece

Leonidas Klironomos - tel:+30 213 2040 327

Clinical Trials Dept./Pharmaceutical Studies & Research Division

National Organization for Medicines (EOF) - Greece

e-mail: trials@eof.gr



España / Spain

M^a Concepción Rodríguez Mateos - tel: +34 91 822 5270, fax: +34 91 822 5289
Agencia Española de Medicamentos y Productos Sanitarios
C/ Campezo 1, Edificio 8, ES - 28022 Madrid
E-mail: psinvclinic@aemps.es - [Web site](#)



France

Agence nationale de sécurité du médicament et des produits de santé (ANSM)
143-147 boulevard Anatole France, FR - 93285 Saint Denis Cedex
E-mail: EC.DM-COS@ansm.sante.fr



Italia / Italy

Ministry of Health
Directorate General of Medical Devices and Pharmaceutical Services
via Giorgio Ribotta 5, IT - 00144 Roma
E-mail: a.colliardo@sanita.it, p.colletti@sanita.it, d.croce@sanita.it, r.sorrentino@sanita.it



Kypros / Kibris / Cyprus

Christiana Valianti - tel:+357 22 605574, fax:+357 22 468427
Cyprus Medical Devices Competent Authority
Prodromou 1 & Chilonos 17 Corner, CY - 1449 Nicosia,
E-mail: cymda@mphs.moh.gov.cy



Latvija / Latvia

Andis Vilums - tel: +371 67 078 466, fax: +371 67078428
State Agency of Medicines, Department of Medical Devices Assessment
15 Jersikas Str. Riga, LV-1003
E-mail: andis.vilums@zva.gov.lv



Lietuva / Lithuania

Director: **Nora Ribokiene** - tel:+370 5 261 51 77, fax:+370 5 212 73 10
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

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

Malta Medicines Authority - Medical Devices Unit
Medicines Authority
Sir Temi Żammit Buildings, Malta Life Sciences Park San Ġwann SĠN 3000, Malta
Tel : +356 2343 9000
E-mail : devices.medicinesauthority@gov.mt - [Web site](#)



Magyarország / Hungary

Kornel Szerdi dr.- tel:+36 1 886 9329
National Institute of Pharmacy and Nutrition (OGYÉI), Department of Medical Devices
1135, Budapest, Szabolcs street 33, Hungary (Mail: 1372 P.O. Box: 450.)
E-mail: ivd@ogyei.gov.hu



Nederland / Netherlands

Dr. Anneriet Heemskerk, ir. Pim Pellikaan
Central Committee on Research Involving Human Subjects (CCMO)
National Clinical Trial Office
Visitor's address: Parnassusplein 5 | 2511 VX | The Hague
Postal address: PO Box 16302 | 2500 BH | The Hague, tel:+31 70 340 6700
E-mail: devices@ccmo.nl – Website



Österreich / Austria

Dr. Stefan Strasser

tel: +43 50 555 36827

Department Clinical Trials, Institute Surveillance

BASG - Bundesamt für Sicherheit im Gesundheitswesen

AGES - Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH

Traisengasse 5, A-1200 Wien | Vienna

E-mail: clinicaltrials@basg.gv.at



Polska / Poland

Andrzej Karczewicz - tel: +48 22 492 11 90

Beata Koziołemska - tel: +48 22 492 11 68

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

Al. Jerozolimskie 181C, 02-222 Warsaw, fax: +48 22 492 11 99

E-mail: incydenty@urpl.gov.pl



Portugal

Infarmed - National Authority of Medicines and Health Products, IP Health Products Directorate

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

E-mail: clinicalstudies.devices@infarmed.pt



Romania

National Agency for Medicines and Medical Devices of Romania

58, Sos. Nicolae Titulescu, sector 1, Bucharest

E-mail: drasp@anm.ro; dgdm@anm.ro - [Web site](#)



Slovenija / Slovenia

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

Slovenčeva ulica 22, 1000 Ljubljana - tel: +386 8 2000 500

E-mail: info@jazmp.si - [Web site](#)



Slovenska Republika / Slovakia

State Institute for Drug Control, Medical Devices Section

Kvetná 11, SK-825 08 Bratislava

E-mail: pomocky@sukl.sk - [Web site](#)



Suomi / Finland

**Finnish Medicines Agency Fimea
Medical Devices Unit**

Mannerheimintie 166, P.O. Box 55, FI-00034 FIMEA, FINLAND, tel:+358 29 522 3602

E-mail: cie@fimea.fi, registry@fimea.fi - [Web site](#)



Sverige / Sweden

**Swedish Medical Products Agency 'Läkemedelsverket'
Department of Clinical Trials and Special Permissions**

Box 26, SE-751 03 Uppsala, tel:+46 18 174600

E-mail: registrator@lakemedelsverket.se - [Web site](#)



Norway / Norge

Statens legemiddelverk/ Norwegian Medicines Agency

Postboks 6167 Etterstad, N-0602 Oslo, tel:+47 22 89 77 00

E-mail: meddev-no@legemiddelverket.no - [Web site](#)



Iceland / Island

MDR-IVDR Icelandic Medicines Agency - tel:+354 520 2100
Vínlandsleið 14, IS-113 Reykjavík
E-mail: ima@ima.is - medical.devices@lyfjastofnun.is - [Web site](#)



Liechtenstein

Martin Stricker - tel:+423 236 7336
Office of Public Health
Äulestrasse 51, Postfach 684, FL - 9490 Vaduz
E-mail: medical.devices@llv.li - [Web site](#)



Turkey

Turkish Medicines and Medical Devices Agency (TITCK)
Ministry of Health
Söğütözü Mahallesi 2176. Sokak No:5 P.K. 06520 Çankaya Ankara/ TURKEY
E-mail: md.ci@titck.gov.tr