

Medical Devices Section (ZP)

tel.: +420 272 185 293

e-mail: [szp\(at\)sukl.cz](mailto:szp(at)sukl.cz)



Please address expert questions to the below-listed units.

LEGAL SUPPORT UNIT (PPZ) <i>Legal support of the Medical Devices Section.</i>	
PPZ Assistant	
	+420 272 185 969
	ppz@sukl.cz
MEDICAL DEVICES REIMBURSEMENT UNIT (UZP) <i>Categorisation and reimbursement regulation of medical devices prescribed on voucher.</i>	
	+420 272 185 971
	uhrzp@sukl.cz
UNIT OF SYSTEMS (SYS) <i>RZPRO (Medical Device Registry) and ISZP (Medical Device Information System) administration and methodological support. Information on the EUDAMED database and medical device regulation in the EU.</i>	
SYS Assistant	
	+420 272 185 125
	sys@sukl.cz
RZPRO info-line	
	+420 272 185 262 Wednesday 8:00 AM – 11:00 AM
	szp_rzpro_dotazy@sukl.cz

EXPERT ACTIVITIES DEPARTMENT (OEČ)	
OEČ Assistant	
	+420 272 185 293
	odbor_oec@sukl.cz
MEDICAL DEVICES CLINICAL EVALUATION UNIT (KHZP)	
<i>Processing of applications for clinical investigations conduct authorisation, performance studies authorisation and substantial modification of clinical investigation approval.</i>	
KHZP Assistant	
	+420 272 185 940
	khzp@sukl.cz
EXPERT OPINIONS UNIT (OPC)	
<i>Issuance of expert opinions in the area of product nature assessment and in the area of medical device and IVD classification.</i>	
OPC Assistant	
	+420 272 185 940
	opc@sukl.cz
REGISTRATION AND NOTIFICATION UNIT (RAN)	
<i>Registration of persons, notification of medical devices and issuance of certificates of free sale.</i>	
RAN Assistant	
	+420 272 185 221
	ran@sukl.cz
Expert queries	
	+420 272 185 600 Monday and Wednesday: 9:00 AM – 11:00 AM, 01:00 PM – 03:00 PM

MARKET SURVEILLANCE DEPARTMENT (ODZP)	
ODZP Assistant	
	+420 272 185 293
	odzp@sukl.cz
MEDICAL DEVICES MARKET SURVEILLANCE UNIT (KON)	
<i>The conduct of surveillance activities in respect of persons handling medical devices pursuant to the Act on Medical Devices and pursuant to the Act on Technical Requirements for Products – inspections of healthcare service providers, manufacturers, authorised representatives, importers, distributors, persons servicing, dispensing, and selling medical devices, including medical device mail-order dispensing inspections, investigations and penalisation.</i>	
KON Assistant	
	+420 272 185 831
	kon@sukl.cz
MEDICAL DEVICES ADVERTISING SURVEILLANCE UNIT (DRZP)	
<i>Performance of national surveillance over compliance with Act No 40/1995 Coll., on Advertising Regulation and on Amendments to Act No 468/1991 Coll., on the Operation of Radio and Television Broadcasting, as amended, in the area of medical devices.</i>	
DRZP Assistant	
	+420 272 185 831
	drzp@sukl.cz
MEDICAL DEVICES VIGILANCE UNIT (VIG)	
<i>Reporting and evaluation of serious incidents and field safety corrective actions.</i>	
VIG Assistant	
	+420 272 185 839 / 118
	vigzp@sukl.cz