

DATA OWNER

NCA name: Štátny ústav pre kontrolu lie#iv	Address: Kvetná 11 825 08 Bratislava 26 Slovakia	Contact person:
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REGISTRATION DATA

Local NCA reference no.: P2028A	Version no.: 1
EUDAMED REFERENCE: DVC-SK-21-01-000003	Record creation date: 2021-01-29
Status code: Created	Status Comments:

DEVICE DATA

GMDN Term: Full-body CT system	GMDN Code: 37618	Other nomenclature:
Make: Softvér Botkin.AI software	Model:	Device also marketed as (trade name):
Class: I	Type: CE marking	
English description: Botkin.AI software is intended to visualize and accompany screening studies, to ensure quality control of the description of medical diagnostic studies in the field of radiology, including a deeper analysis of lung CT, lung X-ray, mammography	Local language: SLOVAK	Local language description: Botkin.AI software je ur#ená na vizualizáciu a skr#ning rádiologických snímok s cie#om zabezpe#i# kontrolu kvality opisu rádiologických snímok pre diagnostické ú#ely v oblasti rádiológie vrátane hlbšej analýzy CT p#úc, röntgenového vyšetrenia p#úc a mamografie
Generic Name:	Outcome of Perf. Eval:	
Comments:		
Device known to be in the market in: SK from 2021-01-29		

ACTOR DATA

Manufacturer name: Intellogic Limited Liability Company	Address: Skolokovo Inovation Centre 334/wp63, Bolshoy Bulvar 42, Bld. 1 Moscow 121205 Russian Federation	Contact person:
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Authorized rep. name: Mgr. Roman Oravec, s.r.o.	Address: SNP 1471/117 Považská Bystrica 017 01 Slovakia	Contact person:
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