

RE: South Korea's MFDS Releases Draft Subcategories for Software Products

Final guidance is expected soon as the MFDS released the following list of Software Product Types and collected feedback until September 16, 2020. The draft risk classification can be found in the [brackets].

## [Category E: Software]

E01000 Software for cardiovascular

E01010.01 [2] Cardiovascular image, treatment planning software

E01010.02 [2] Cardiovascular image, analysis software

E01020.01 [2] Electrocardiograph, analysis software

E01020.02 [2] Electrocardiograph, mobile analysis software

E01030.01 [2] Blood flow, analysis software

E01040.01 [2] Cardiac output, analysis software

E01050.01 [2] Oxygen saturation, analysis software

E01050.02 [2] Oxygen saturation, mobile analysis software

E01060.01 [2] Blood gas, analysis software

E01070.01 [2] Blood pressure, analysis software

E01070.02 [2] Blood pressure, mobile analysis software

E01080.01 [2] Heart rate, analysis software

E01080.02 [2] Heart rate, mobile analysis software

E01090.01 [2] Pulse wave, analysis software

E01090.02 [2] Pulse wave, mobile analysis software

E01100.01 [3] Cardiopulmonary physiology, analysis software

E01110.01 [3] Cardiovascular risk assessment software

E01120.01 [3] Cardiovascular image, computer aided detection/ diagnosis software

E02000 Software for dental

E02010.01 [1] Dental image, Picture archiving and communication system, software, class 1

E02010.02 [2] Dental image, Picture archiving and communication system, software, class 2

E02020.01 [2] Dental image, treatment planning software

E02020.02 [2] Dental image, analysis software

E02030.01 [2] Dental image, computer aided detection/diagnosis software

E03000 Software for otolaryngology

E03010.01 [2] Impedance audiometer, analysis software

E03020.01 [2] Evoked-response audiometer, analysis software

E03030.01 [2] Equilibrium function, analysis software

E03040.01 [2] Larynx function, analysis software

E03050.01 [2] Audiometer software

E04000 Software for gastroenterology and urology

E04010.01 [2] Endoscopic image, treatment planning software

E04010.02 [2] Endoscopic image, analysis software

E04020.01 [2] Endoscopic image, computer aided detection/ diagnosis software

E04020.02 [3] Gastric cancer image, computer aided detection/ diagnosis software

E04020.03 [3] Colorectal cancer image, computer aided detection/ diagnosis software

E04020.04 [3] Prostate cancer image, computer aided detection/ diagnosis software

## E05000 Software for general hospital

- E05010.01 [2] Infusion safety management software
- E05020.01 [2] Vital sign, analysis software
- E05020.02 [2] Polysomnograph, vital sign, analysis software
- E05030.01 [2] Bone absorptiometric ultrasound, analysis software
- E05040.01 [2] Ultrasound image, treatment planning software
- E05040.02 [2] Ultrasound image, analysis software
- E05050.01 [2] Ultrasound image, computer aided detection/diagnosis software, class 2
- E05050.02 [3] Ultrasound image, computer aided detection/diagnosis software, class 3
- E05060.01 [2] Near infrared camera image, analysis software
- E05070.01 [2] Wound image, analysis software
- E05080.01 [2] Lungcapacity, analysis software
- E05080.02 [2] Pulmonary exercise stress, analysis software
- E05090.01 [2] Respiratory gas, analysis software
- E05090.02 [2] Respiratory function, analysis software
- E05090.03 [2] Respiratory resistance, analysis software
- E05090.04 [2] Respiratory mobile analysis software
- E05100.01 [2] Body temperature, mobile analysis software
- E05110.01 [1] U-healthcare gateway software, class 1
- E05110.02 [2] U-healthcare gateway software, class 2
- E05110.03 [3] U-healthcare, decision support software

## E06000 Software for neurology

- E06010.01 [2] Electroencephalograph, analysis software
- E06010.02 [2] Magnetoencephalograph, analysis software
- E06020.01 [2] Neural image, treatment planning software
- E06020.02 [2] Neural image, analysis software
- E06030.01 [2] Ataxiagraph, analysis software
- E06040.01 [2] Parkinson's disease exercise aided software
- E06050.01 [2] Psychological assessment software
- E06060.01 [2] Cognitive assessment software
- E06060.02 [2] Cognitive therapy software
- E06070.01 [2] Affective disorder therapy software
- E06080.01 [2] Evoked response, analysis software
- E06090.01 [3] Neural image, computer aided detection/diagnosis software

## E07000 Software for uterology

- E07010.01 [2] Fertility, computer aided diagnosis software
- E07020.01 [2] Vital sign fetal, analysis software
- E07020.02 [2] Ultrasonic fetal heart, analysis software
- E07030.01 [3] Congenital defect risk assessment software

## E08000 Software for ophthalmology

- E08010.01 [2] Ophthalmic image, treatment planning software
- E08010.02 [2] Ophthalmic image, analysis software
- E08020.01 [3] Ophthalmic image, computer aided detection/ diagnosis software
- E08030.01 [2] Vision training software

E09000 Software for orthopedics

E09010.01 [2] Orthopedic image, treatment planning software

E09010.02 [2] Orthopedic image, analysis software

E09020.01 [2] Orthopedic image, computer aided detection/ diagnosis software

E10000 Software for rehabilitation

E10010.01 [2] Electromyograph, analysis software

E10020.01 [2] Respiratory rehabilitation, software

E10020.02 [3] Cardiopulmonary rehabilitation software

E11000 Software for radiation oncology and diagnostic radiology

E11010.01 [1] Medical image, mobile picture archiving and communication system, software

E11010.02 [1] Medical image, picture archiving and communication system, software, class 1

E11010.03 [2] Medical image, picture archiving and communication system, software, class 2

E11020.01 [2] Medical image, treatment planning software

E11020.02 [2] Medical image, analysis software

E11020.03 [2] Medical image, radiation treatment planning software

E11030.01 [2] Medical image, computer aided detection/ diagnosis software, class 2

E11030.02 [3] Medical image, computer aided detection/ diagnosis software, class 3

E11030.03 [3] Breast cancer image, computer aided detection/ diagnosis software

E11040.01 [3] Cancer risk assessment software