



**SG Healthcare Co., Ltd.**

10, Yangnyeong-ro, Moga-myeon,  
Icheon-si, Gyeonggi-do, 17408,  
Republic of Korea

**Attn. Kim Jung-Su / CEO**

**Our reference**

MIT/2024/P043.2

**Contact person**

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BRATISLAVA

05.12.2024

**Subject: Notified Body Confirmation Letter**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as amended as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, **3EC International a.s.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2265 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

SG Healthcare Co., Ltd.

10, Yangnyeong-ro, Moga-myeon,  
Icheon-si, Gyeonggi-do, 17408,  
Republic of Korea

SRN Number (if available): KR-MF-000011322

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices

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Tel/Fax: 00421 (0)2 5831 8343 / - 45 e-mail: info@3ec.sk web: http://www.3ec.sk

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- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,



3EC International a. s. ©  
 Hraničná 18, 821 05 Bratislava  
 Slovak Republic  
 ID No.: 36 789 003  
 VAT No.: SK2022390073

**Katarína Tomin Srdošová, PhD.**

Director of NB2265

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Analog X-ray System</b> Model: JUMONG GENERAL	Class IIb excluding Class IIb implantable non-WET	N/A	0068/QCO-MD/092-2018, NB0068
<b>Digital X-ray System</b> Models: JUMONG, JUMONG X (X: A~Z)	Class IIb excluding Class IIb implantable non-WET	N/A	0068/QCO-MD/092-2018, NB0068
<b>Medical Image Processing Unit (Flat panel detector)</b> Models: JUMONG RETRO, JUMONG RETRO COMFORT, JUMONG MOBILE	Class IIa	N/A	0068/QCO-MD/092-2018, NB0068
<b>X-Ray Equipment for computed tomography</b> Model: DOMINUS	Class IIb excluding Class IIb implantable non-WET	N/A	0068/QCO-MD/092-2018, NB0068

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

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## Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/02/01	MIT/2024/P043	Initial issue
2024/09/26	MIT/2024/P043.1	<p>Due to the fact, that article 120 (3e) of MDR became effective, 3EC International a.s. is taking responsibility for the appropriate surveillance audit in respect of the medical devices covered by the written agreement SK-0776-MDR/24 between manufacturer SG Healthcare Co., Ltd. and incoming notified body 3EC International a.s.</p> <p>Class IIa Analog X-ray System Model: JUMONG GENERAL, issued under MDD certificate No. 0068/QCO-MD/092-2018,</p> <p>Class IIa Digital X-ray System Models: JUMONG, JUMONG X (X: A-Z), issued under MDD certificate No. 0068/QCO-MD/092-2018,</p> <p>Class IIa Medical Image Processing Unit (Flat panel detector) Models: JUMONG RETRO, JUMONG RETRO COMFORT, JUMONG MOBILE, issued under MDD certificate No. 0068/QCO-MD/092-2018,</p> <p>Class IIa X-Ray Equipment for computed tomography Model: DOMINUS, issued under MDD certificate No. 0068/QCO-MD/092-2018.</p>
2024/12/05	MIT/2024/P043.2	<p>Changing of class in devices Analog X-ray System Model: JUMONG GENERAL, Digital X-ray System Models: JUMONG, JUMONG X (X: A-Z) and X-Ray Equipment for computed tomography Model: DOMINUS issued under MDD certificate No. 0068/QCO-MD/092-2018 from Class IIa to Class IIb excluding Class IIb implantable non-WET because of typo mistake in the extension confirmation letter.</p>