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To whom it may concern

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I hereby confirm that below listed devices are within the scope of certificate EC - G1 09 09 46135 023 issued by TUV-SUD Product Service GmbH.

No.	Product	UMDNS CODE	Model Name	Class	Rule	Conformity Assessment Route	Cleared EC Certificate No.
1	Syringe Pumps	13217	PION TCI		Rule11		
2	Patient Monitors	12636	BM1 / GIMA BM1	IIb	Rule10	93/42/EEC Annex.II.3	G1 09 09 46135 023
3			BM3 / GIMA BM3				
4			BM3 Plus				
5			BM3 Wide				
6			BM3 Lite				
7			BM5 / BM5 CS / BM5 CX / GIMA BM5				
8			Patient Monitoring Central System				

If you have any questions, please feel free to contact us.

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No.	Product	UMDNS CODE	Model Name	Class	Rule	Conformity Assessment Route	Cleared EC Certificate No.
9	ECG Re-corder	12387	CardioCare 2000 / EKG-2000 / Cardio GIMA 12	IIa	Rule10	93/42/EEC Annex.II.3	G1 09 09 46135 023
10			CardioTouch 3000 / EKG-3000 / Cardio GIMA 12M				
11	ECG Re-corder, Spirometers	13674	CardioTouch 3000S / EKG-3000S				
12			CardioXP / GIMA CardioXP 12 Channel ECG				
13	Spirometers	13674	SPM-300				
14	Pocket Dopplers	11696	BabyCare				
15	Fetal Monitors	12610	FC 700 / FETAL MONITOR GIMA FC 700				
16			FC 1400 / FETAL MONITOR GIMA FC 1400				
17			FetalXP				
18			Fetal Monitoring Central System	FC Central			

If you have any questions, please feel free to contact us.

Yours faithfully,

Woo Sung Park / Lead Auditor

Medical-Health-Services/ TÜV SÜD Korea Ltd.