

JEILMEDICAL	Technical Construction File	Doc. No.	TCF01-1
		Rev. No.	1
	1. Declaration of Conformity	Issue Date	2020-03-05
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EC Declaration of Conformity

Manufacturer: Jeil Medical Corporation
702-703-704-705-706-804-805-807-812-815-ho,
55, Digital-ro 34-gil, Guro-Gu, Seoul, 152-728 Korea

MDD Certificate Number: KR19/81826303
EC Representative: EMERGO EUROPE
Prinsessegracht 20, 2514 AP, The Hague, The Netherlands

Declares that the medical device described hereafter

The Leforte System has been classified as Class IIb (Annex IX Rule 8) and are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by MDD 2007/47/EC.

It is in conformity with the international standard EN ISO 14630:2009: Non-active Surgical Implants.

It is subject to the procedure set out in Annex II (excluding Section 4) of Directive 93/42/EEC as amended by MDD 2007/47/EC under the supervision of SGS Belgium NV, Notified Body 1639, SGS House Noorderlaan 87, 2030, Antwerpen, Belgium.

Korea / March 05, 2020
Annex A. List of Product with Class IIb



Quality Management Representative
Jeil Medical Corporation

[Annex A]

List of Products with Class IIb

- Bone Plate

No.	Product Code	No.	Product Code	No.	Product Code
1	12-CD-006	31	12-ME-001-04	61	12-YP-008
2	12-CD-008	32	12-ME-001-05	62	16-CD-006
3	12-CD-012	33	12-ME-002-01	63	16-CD-008
4	12-CV-001	34	12-ME-002-02	64	16-CD-010
5	12-CV-002	35	12-ME-002-03	65	16-CV-006
6	12-CV-003	36	12-ME-002-04	66	16-CV-106
7	12-CV-004	37	12-ME-002-05	67	16-DL-003
8	12-DY-006	38	12-ME-003-01	68	16-DL-007
9	12-DY-106	39	12-ME-003-02	69	16-DL-012
10	12-GM-001-01	40	12-ME-003-03	70	16-DY-006
11	12-GM-001-02	41	12-ME-003-04	71	16-DY-106
12	12-GM-002-01	42	12-ME-003-05	72	16-HP-006
13	12-GM-002-02	43	12-QD-008	73	16-HP-004
14	12-HP-006	44	12-QD-008-S	74	16-LL-004
15	12-HP-012	45	12-QD-008-W	75	16-LL-104
16	12-HX-001	46	12-QD-108	76	16-LL-204
17	12-HX-002	47	12-SQ-004	77	16-LL-304
18	12-HX-003	48	12-SQ-104	78	16-LL-406
19	12-HX-102	49	12-ST-002	79	16-LR-004
20	12-LL-004	50	12-ST-004	80	16-LR-104
21	12-LL-008	51	12-ST-005	81	16-LR-204
22	12-LL-104	52	12-ST-006	82	16-LR-304
23	12-LL-134	53	12-ST-008	83	16-LR-406
24	12-LR-004	54	12-ST-018	84	16-ME-001
25	12-LR-008	55	12-ST-102	85	16-ME-002
26	12-LR-104	56	12-TP-005	86	16-OR-C10-02
27	12-LR-134	57	12-TP-010	87	16-OR-C10-03
28	12-ME-001-01	58	12-XP-005	88	16-OR-F10-02
29	12-ME-001-02	59	12-YP-005	89	16-OR-F10-03
30	12-ME-001-03	60	12-YP-007	90	16-OR-V10-02

No.	Product Code
91	16-OR-V10-03
92	16-OR-V20-02
93	16-OR-V20-03
94	16-QD-006
95	16-QD-006-S
96	16-QD-010-S
97	16-QD-036-S
98	16-QD-106
99	16-RCL-000
100	16-RCL-002
101	16-RCL-004
102	16-RCL-006
103	16-RCL-008
104	16-RCL-010
105	16-RCL-012
106	16-RCR-000
107	16-RCR-002
108	16-RCR-004
109	16-RCR-006
110	16-RCR-008
111	16-RCR-010
112	16-RCR-012
113	16-SQ-004
114	16-SQ-004-S
115	16-SQ-034
116	16-SQ-034-S
117	16-SQ-144
118	16-SQ-144-S
119	16-SQ-234B0
120	16-SQ-234B2
121	16-SQ-234B3
122	16-SQ-234B4
123	16-SQ-234B5
124	16-SQ-234B7
125	16-ST-002
126	16-ST-002K

No.	Product Code
127	16-ST-002-R
128	16-ST-003K
129	16-ST-004
130	16-ST-006
131	16-ST-010
132	16-ST-012
133	16-ST-012-R
134	16-ST-018
135	16-ST-102
136	16-ST-102-R
137	16-ST-104
138	16-ST-116
139	16-ST-202-F
140	16-ST-302B0
141	16-ST-302B2
142	16-ST-302B3
143	16-ST-302B4
144	16-ST-302B5
145	16-ST-432
146	16-ST-442
147	16-YP-005
148	16-ZL-004
149	16-ZL-104
150	16-ZR-004
151	16-ZR-104
152	20-AJ-004
153	20-AJ-006
154	20-AJ-006C1
155	20-AJ-008
156	20-AJ-010
157	20-CD-004C1
158	20-CD-005
159	20-CD-007
160	20-CD-009
161	20-CD-020
162	20-CD-104

No.	Product Code
163	20-CD-105
164	20-CD-204
165	20-CH-000
166	20-CH-000C1
167	20-CH-000C3
168	20-CH-001
169	20-CH-001C1
170	20-CH-001C3
171	20-CH-002
172	20-CH-002C1
173	20-CH-002C2
174	20-CH-002C3
175	20-CH-002C4
176	20-CH-003
177	20-CH-003C1
178	20-CH-003C3
179	20-CH-004
180	20-CH-004C1
181	20-CH-004C3
182	20-CH-005
183	20-CH-006
184	20-CH-006C1
185	20-CH-006C3
186	20-CH-007
187	20-CH-008
188	20-CH-008C1
189	20-CH-008C3
190	20-CH-010
191	20-CH-012
192	20-CN-004
193	20-CN-004-S
194	20-CN-009
195	20-CN-009-S
196	20-CP-004
197	20-CP-005
198	20-CV-006-F

No.	Product Code
199	20-CV-006-R
200	20-CV-026
201	20-CV-106-F
202	20-CV-106-R
203	20-CV-126
204	20-DB-009
205	20-DB-012
206	20-DH-001
207	20-DH-002
208	20-DH-003
209	20-DR-003
210	20-DR-008
211	20-DR-013
212	20-DR-018
213	20-DY-026
214	20-DY-126
215	20-IP-004-F
216	20-IP-004-R
217	20-IP-024
218	20-L-AL-015
219	20-L-AR-015
220	20-L-CD-005
221	20-L-CD-007
222	20-L-CD-009
223	20-LL-004-F
224	20-LL-004-R
225	20-LL-024
226	20-LL-024-S
227	20-LL-104-F
228	20-LL-104-R
229	20-LL-124
230	20-LL-124-S
231	20-LL-134
232	20-LL-134-R
233	20-LL-204-F
234	20-LL-204-R

No.	Product Code
235	20-LL-224
236	20-LL-224B1
237	20-LL-224B2
238	20-LL-224B3
239	20-LL-224B4
240	20-LL-224B5
241	20-LL-224B6
242	20-LL-224B7
243	20-LL-224B8
244	20-LL-224-S
245	20-LL-224-W
246	20-LL-234
247	20-LL-234B1
248	20-LL-234B2
249	20-LL-234B3
250	20-LL-234B4
251	20-LL-234B5
252	20-LL-304-F
253	20-LL-304-R
254	20-LL-324
255	20-LL-334
256	20-LL-404-F
257	20-LL-404-R
258	20-LL-424
259	20-LL-434
260	20-LL-524-S
261	20-LP-004
262	20-LP-004-R
263	20-LP-104
264	20-LP-104-R
265	20-LP-204
266	20-LP-204-R
267	20-LP-304
268	20-LP-304-R
269	20-LP-404
270	20-LP-404-R

No.	Product Code
271	20-LR-004-F
272	20-LR-004-R
273	20-LR-024
274	20-LR-024-S
275	20-LR-104-F
276	20-LR-104-R
277	20-LR-124
278	20-LR-124-S
279	20-LR-134
280	20-LR-134-R
281	20-LR-204-F
282	20-LR-204-R
283	20-LR-224
284	20-LR-224B1
285	20-LR-224B2
286	20-LR-224B3
287	20-LR-224B4
288	20-LR-224B5
289	20-LR-224B6
290	20-LR-224B7
291	20-LR-224B8
292	20-LR-224-S
293	20-LR-224-W
294	20-LR-234
295	20-LR-234B1
296	20-LR-234B2
297	20-LR-234B3
298	20-LR-234B4
299	20-LR-234B5
300	20-LR-304-F
301	20-LR-304-R
302	20-LR-324
303	20-LR-334
304	20-LR-404-F
305	20-LR-404-R
306	20-LR-424

No.	Product Code
307	20-LR-434
308	20-LR-524-S
309	20L-RL-020
310	20L-RM-025
311	20L-RR-020
312	20L-RS-015
313	20L-RS-021
314	20L-RS-025
315	20L-SB-004
316	20L-SB-104
317	20L-SB-204
318	20L-ST-004-R
319	20L-ST-006-R
320	20L-ST-006-R10
321	20L-ST-006-R15
322	20L-ST-010-R
323	20L-ST-016-R
324	20L-ST-018-R
325	20L-ST-104-R
326	20-ME-001
327	20-ME-002
328	20-ME-018
329	20-MG-005
330	20-MG-007
331	20-MG-010
332	20-MG-015
333	20-SB-004
334	20-SB-004-E
335	20-SB-104
336	20-SB-104-E
337	20-SB-204
338	20-SB-204-E
339	20-SJ-009
340	20-SJ-012
341	20-SJ-018
342	20-SJ-021

No.	Product Code
343	20-SJ-109
344	20-SJ-112
345	20-SJ-209
346	20-SJ-212
347	20-SQ-004-F
348	20-SQ-004-R
349	20-SQ-004-S
350	20-SS-008
351	20-SS-013
352	20-SS-018
353	20-ST-003C1
354	20-ST-004
355	20-ST-004C1
356	20-ST-004-F
357	20-ST-004-M
358	20-ST-004-R
359	20-ST-005-E10
360	20-ST-005-E15
361	20-ST-005-R10
362	20-ST-005-R15
363	20-ST-006
364	20-ST-006-F
365	20-ST-006-M
366	20-ST-006-R
367	20-ST-008
368	20-ST-008-F
369	20-ST-008-M
370	20-ST-008-R
371	20-ST-010
372	20-ST-010-F
373	20-ST-010-R
374	20-ST-016
375	20-ST-016-F
376	20-ST-016-M
377	20-ST-016-R
378	20-ST-017

No.	Product Code
379	20-ST-017-R
380	20-ST-018C1
381	20-ST-018C2
382	20-ST-018-M
383	20-ST-018-R
384	20-ST-019
385	20-ST-019-R
386	20-ST-020
387	20-ST-034-M
388	20-ST-103
389	20-ST-104
390	20-ST-104-E
391	20-ST-104-F
392	20-ST-104-R
393	20-ST-106-R
394	20-ST-114-E
395	20-ST-114-R
396	20-ST-116-M
397	20-ST-124
398	20-ST-134
399	20-ST-203
400	20-ST-224
401	20-ST-324
402	20-TP-005-F
403	20-TP-005-M
404	20-TP-005-R
405	20-XP-004-F
406	20-XP-004-R
407	20-YJ-005C1
408	20-YJ-045C1
409	20-YL-007
410	20-YP-007-F
411	20-YP-007-R
412	20-YP-027
413	20-YR-007
414	20-ZL-004-F

No.	Product Code
415	20-ZL-004-R
416	20-ZL-024
417	20-ZL-034
418	20-ZL-104-F
419	20-ZL-104-R
420	20-ZL-124
421	20-ZL-134
422	20-ZP-004B0
423	20-ZP-004B1
424	20-ZP-004B2
425	20-ZP-004B3
426	20-ZP-004B4
427	20-ZR-004-F
428	20-ZR-004-R
429	20-ZR-024
430	20-ZR-034
431	20-ZR-104-F
432	20-ZR-104-R
433	20-ZR-124
434	20-ZR-134
435	242.10CD06
436	242.10CD08
437	242.10CD12
438	242.10CV06
439	242.10DY06
440	242.10HP06
441	242.10HP12
442	242.10LL04
443	242.10LR04
444	242.10QD08
445	242.10SQ04
446	242.10ST02
447	242.10ST04
448	242.10ST05
449	242.10ST06
450	242.10ST08

No.	Product Code
451	242.10ST18
452	242.10ST20
453	242.10TP05
454	242.10TP10
455	242.10XP05
456	242.10YP05
457	242.10YP07
458	242.10YP08
459	242.11CV06
460	242.11DY06
461	242.11LL04
462	242.11LR04
463	242.11QD08
464	242.11SQ04
465	242.11ST02
466	242.11YP08
467	242.12CV06
468	242.12QD08
469	242.13CV06
470	242.20CD06
471	242.20CD08
472	242.20CD10
473	242.20CD12
474	242.20CV06
475	242.20DY06
476	242.20HP06
477	242.20IP04
478	242.20LL04
479	242.20LR04
480	242.20QD06
481	242.20SQ04
482	242.20ST02
483	242.20ST04
484	242.20ST06
485	242.20ST12
486	242.20ST20

No.	Product Code
487	242.20YP05
488	242.20ZL04
489	242.20ZR04
490	242.21CV06
491	242.21DY06
492	242.21LL04
493	242.21LR04
494	242.21QD06
495	242.21SQ04
496	242.21ST02
497	242.21ST04
498	242.21ZL04
499	242.21ZR04
500	242.22LL04
501	242.22LR04
502	242.22QD06
503	242.22ST02
504	242.23LL04
505	242.23LL06
506	242.23LR04
507	242.23LR06
508	242.30CH04.B2
509	242.30CH04.B3
510	242.30CH04.B4
511	242.30CH04.B5
512	242.30CH04.B6
513	242.30CH04.B7
514	242.30CH04.B8
515	242.30CP04.02
516	242.30CP05.02
517	242.30CP06.02
518	242.30CV06
519	242.30IP04
520	242.30LL04
521	242.30LP04
522	242.30LP04.01

No.	Product Code
523	242.30LR04
524	242.30SQ04
525	242.30ST04
526	242.30ST06
527	242.30ST08
528	242.30ST10
529	242.30ST16
530	242.30ST17
531	242.30ST18
532	242.30ST19
533	242.30ST20
534	242.30XP04
535	242.30YP05
536	242.30YP06
537	242.30YP07
538	242.30YP08
539	242.31CV06
540	242.31LL04
541	242.31LL14
542	242.31LP04
543	242.31LP04.01
544	242.31LR04
545	242.31LR14
546	242.31ST04
547	242.32LL04
548	242.32LP04
549	242.32LP04.01
550	242.32LR04
551	242.32ST04
552	242.33LL04
553	242.33LP04
554	242.33LP04.01
555	242.33LR04
556	242.33ST04
557	242.34LL04
558	242.34LP04

No.	Product Code
559	242.34LP04.01
560	242.34LR04
561	242.50AE06.03
562	242.50AJ10.02
563	242.50AJ12.02
564	242.50AJ14.02
565	242.50AJ16.02
566	242.50CD05
567	242.50CD05.01
568	242.50CD07
569	242.50CD07.01
570	242.50CD09
571	242.50CD09.01
572	242.50CH13
573	242.50CN04.01
574	242.50CN09.01
575	242.50CV06
576	242.50CV06.01
577	242.50DR06
578	242.50DR16
579	242.50IP04
580	242.50IP04.01
581	242.50LL04
582	242.50LL04.01
583	242.50LL06
584	242.50LL16
585	242.50LR04
586	242.50LR04.01
587	242.50LR06
588	242.50LR16
589	242.50QD06.02
590	242.50QD08.02
591	242.50SP06.01
592	242.50SP16.01
593	242.50SQ04
594	242.50SQ04.01

No.	Product Code
595	242.50SQ04.02
596	242.50SS06
597	242.50SS16
598	242.50ST04
599	242.50ST04.01
600	242.50ST04.04
601	242.50ST06
602	242.50ST06.01
603	242.50ST06.04
604	242.50ST08
605	242.50ST08.01
606	242.50ST10
607	242.50ST10.01
608	242.50ST12.03
609	242.50ST12.04
610	242.50ST16
611	242.50ST16.01
612	242.50ST17
613	242.50ST17.01
614	242.50ST18
615	242.50ST18.01
616	242.50ST19
617	242.50ST19.01
618	242.50ST20
619	242.50ST20.01
620	242.50ST20.04
621	242.50TP11.01
622	242.50XP04
623	242.50XP04.01
624	242.50YL08.B0
625	242.50YL08.B10
626	242.50YL08.B15
627	242.50YL08.B20
628	242.50YL08.B3
629	242.50YL08.B5
630	242.50YL08.B7

No.	Product Code
631	242.50YP05
632	242.50YP05.01
633	242.50YP06
634	242.50YP06.01
635	242.50YP07
636	242.50YP07.01
637	242.50YP08
638	242.50YP08.01
639	242.50YR08.B0
640	242.50YR08.B10
641	242.50YR08.B15
642	242.50YR08.B20
643	242.50YR08.B3
644	242.50YR08.B5
645	242.50YR08.B7
646	242.50ZL04
647	242.50ZL04.01
648	242.50ZR04
649	242.50ZR04.01
650	242.51CD06.03
651	242.51CH13
652	242.51CN04.01
653	242.51CN09.01
654	242.51CR04.03
655	242.51CV06
656	242.51CV06.01
657	242.51DR06
658	242.51DR16
659	242.51LL04
660	242.51LL04.01
661	242.51LL06
662	242.51LL14
663	242.51LL14.01
664	242.51LL16
665	242.51LR04
666	242.51LR04.01

No.	Product Code
667	242.51LR06
668	242.51LR14
669	242.51LR14.01
670	242.51LR16
671	242.51SP06.01
672	242.51SP16.01
673	242.51SS06
674	242.51SS16
675	242.51ST04
676	242.51ST04.01
677	242.51ST04.02
678	242.51ST04.03
679	242.51ST04.04
680	242.51ST06.04
681	242.51TP09.01
682	242.52CH13
683	242.52DR06
684	242.52DR16
685	242.52LL04
686	242.52LL04.01
687	242.52LL04.B1
688	242.52LL04.B2
689	242.52LL04.B3
690	242.52LL04.B4
691	242.52LL04.B5
692	242.52LL04.B6
693	242.52LL04.B7
694	242.52LL04.B8
695	242.52LL06
696	242.52LL14.B1
697	242.52LL14.B2
698	242.52LL14.B3
699	242.52LL14.B4
700	242.52LL14.B5
701	242.52LL14.B6
702	242.52LL14.B7

No.	Product Code
703	242.52LL14.B8
704	242.52LL16
705	242.52LR04
706	242.52LR04.01
707	242.52LR04.B1
708	242.52LR04.B2
709	242.52LR04.B3
710	242.52LR04.B4
711	242.52LR04.B5
712	242.52LR04.B6
713	242.52LR04.B7
714	242.52LR04.B8
715	242.52LR06
716	242.52LR14.B1
717	242.52LR14.B2
718	242.52LR14.B3
719	242.52LR14.B4
720	242.52LR14.B5
721	242.52LR14.B6
722	242.52LR14.B7
723	242.52LR14.B8
724	242.52LR16
725	242.52SP06.01
726	242.52SP16.01
727	242.52SS06
728	242.52SS16
729	242.52ST04
730	242.52ST04.01
731	242.52ST04.02
732	242.52ST04.03
733	242.52ST06.03
734	242.52TP09.01
735	242.53CH13
736	242.53DR06
737	242.53DR16
738	242.53LL04

No.	Product Code
739	242.53LL04.01
740	242.53LL06
741	242.53LL16
742	242.53LR04
743	242.53LR04.01
744	242.53LR06
745	242.53LR16
746	242.53SP06.01
747	242.53SP16.01
748	242.53SS06
749	242.53SS16
750	242.53ST04
751	242.53ST04.01
752	242.53ST04.02
753	242.54CH13
754	242.54LL04
755	242.54LL04.01
756	242.54LR04
757	242.54LR04.01
758	242.54SP06.01
759	242.54SP16.01
760	242.54ST04
761	242.54ST04.01
762	242.54ST04.02
763	242.55CH13
764	242.55SP06.01
765	242.55SP16.01
766	242.56CH13
767	242.56SP06.01
768	242.56SP16.01
769	242.57CH13
770	242.57SP16.01
771	242.58CH13
772	242.60AE04
773	242.60AE06
774	242.60RL14

No.	Product Code
775	242.60RL19
776	242.60RM23
777	242.60RR14
778	242.60RR19
779	242.60RS15
780	242.60RS21
781	242.60RS25
782	242.60SB04
783	242.61AE04
784	242.61CD06
785	242.61RL16
786	242.61RL16.01
787	242.61RL18
788	242.61RL18.01
789	242.61RM23
790	242.61RM23.01
791	242.61RM25
792	242.61RM25.01
793	242.61RR16
794	242.61RR16.01
795	242.61RR18
796	242.61RR18.01
797	242.61RS21
798	242.61RS21.01
799	242.61SB04
800	242.61ST04
801	242.61ST06
802	242.62RL16
803	242.62RL16.01
804	242.62RL18
805	242.62RL18.01
806	242.62RM23
807	242.62RM23.01
808	242.62RM25
809	242.62RM25.01
810	242.62RR16

No.	Product Code
811	242.62RR16.01
812	242.62RR18
813	242.62RR18.01
814	242.62RS21
815	242.62RS21.01
816	242.62ST04
817	242.63ST04
818	242.80AE04
819	242.80AE06
820	242.81AE04
821	242.81CD06
822	242.81SE04
823	242.81SE06
824	242.82SE04
825	24-AE-004
826	24-AE-006
827	24-AE-104
828	24-AL-015
829	24-AR-015
830	24-CD-006
831	24L-AE-004
832	24L-AE-006
833	24L-AE-104
834	24L-AL-015
835	24L-AR-015
836	24L-CD-006
837	24L-RL-020
838	24L-RM-025
839	24L-RR-020
840	24L-RS-015
841	24L-RS-021
842	24L-RS-025
843	24L-ST-006
844	24L-ST-104
845	24-RL-020
846	24-RM-025

No.	Product Code
847	24-RR-020
848	24-RS-015
849	24-RS-021
850	24-RS-025
851	24-SB-004

No.	Product Code
852	24-SB-007
853	24-SB-008
854	24-SB-104
855	24-SB-204
856	24-SE-004

No.	Product Code
857	24-SE-006
858	24-SE-104
859	24-ST-004
860	24-ST-006
861	24-ST-104

- Bone Screw

No.	Product Code
1	241.011302
2	241.011303
3	241.011304
4	241.011305
5	241.011306
6	241.011307
7	241.011308
8	241.011309
9	241.011310
10	241.011311
11	241.011312
12	241.011502
13	241.011503
14	241.011504
15	241.011505
16	241.011506
17	241.011507
18	241.011508
19	241.011509
20	241.011510
21	241.011511
22	241.011512
23	241.011603
24	241.011604
25	241.011605
26	241.011606
27	241.011607

No.	Product Code
28	241.011608
29	241.011609
30	241.011610
31	241.011611
32	241.011612
33	241.011803
34	241.011804
35	241.011805
36	241.011806
37	241.011807
38	241.011808
39	241.011809
40	241.011810
41	241.011811
42	241.011812
43	241.012003
44	241.012004
45	241.012005
46	241.012006
47	241.012007
48	241.012008
49	241.012009
50	241.012010
51	241.012011
52	241.012012
53	241.012013
54	241.012014

No.	Product Code
55	241.012015
56	241.012016
57	241.012017
58	241.012018
59	241.012019
60	241.012020
61	241.012303
62	241.012304
63	241.012305
64	241.012306
65	241.012307
66	241.012308
67	241.012309
68	241.012310
69	241.012311
70	241.012312
71	241.012313
72	241.012314
73	241.012315
74	241.012316
75	241.012317
76	241.012318
77	241.012319
78	241.012320
79	241.012403
80	241.012404
81	241.012405

No.	Product Code
82	241.012406
83	241.012407
84	241.012408
85	241.012409
86	241.012410
87	241.012411
88	241.012412
89	241.012413
90	241.012414
91	241.012415
92	241.012416
93	241.012417
94	241.012418
95	241.012419
96	241.012420
97	241.012703
98	241.012704
99	241.012705
100	241.012706
101	241.012707
102	241.012708
103	241.012709
104	241.012710
105	241.012711
106	241.012712
107	241.012713
108	241.012714
109	241.012715
110	241.012716
111	241.012717
112	241.012718
113	241.012719
114	241.012720
115	241.021403
116	241.021404
117	241.021405

No.	Product Code
118	241.021406
119	241.021407
120	241.021408
121	241.021409
122	241.021410
123	241.021411
124	241.021412
125	241.021603
126	241.021604
127	241.021605
128	241.021606
129	241.021607
130	241.021608
131	241.021609
132	241.021610
133	241.021611
134	241.021612
135	241.022004
136	241.022005
137	241.022006
138	241.022007
139	241.022008
140	241.022009
141	241.022010
142	241.022011
143	241.022012
144	241.032003
145	241.032004
146	241.032005
147	241.032006
148	241.032007
149	241.032008
150	241.032009
151	241.032010
152	241.032011
153	241.032012

No.	Product Code
154	241.032013
155	241.032014
156	241.032015
157	241.032016
158	241.032017
159	241.032018
160	241.032019
161	241.032020
162	241.032403
163	241.032404
164	241.032405
165	241.032406
166	241.032407
167	241.032408
168	241.032409
169	241.032410
170	241.032411
171	241.032412
172	241.032413
173	241.032414
174	241.032415
175	241.032416
176	241.032417
177	241.032418
178	241.032419
179	241.032420
180	12-MC-002
181	12-MC-003
182	12-MC-004
183	12-MC-005
184	12-MC-006
185	12-MC-008
186	12-MC-010
187	12-MC-012
188	14-AT-003
189	14-AT-004

No.	Product Code
190	14-AT-005
191	14-AT-006
192	14-AT-008
193	14-AT-010
194	14-AT-012
195	15-MC-003
196	15-MC-004
197	15-MC-005
198	15-MC-006
199	15-MC-008
200	15-MC-010
201	16-AT-003
202	16-AT-004
203	16-AT-005
204	16-AT-006
205	16-AT-007
206	16-AT-008
207	16-AT-010
208	16-AT-012
209	16-MD-004
210	16-MD-005
211	16-MD-006
212	16-MD-008
213	16-MD-010
214	19-MD-004
215	19-MD-006
216	20-AT-004
217	20-AT-005
218	20-AT-006
219	20-AT-008
220	20-AT-010
221	20-AT-012
222	20-BH-008
223	20-BH-010
224	20-BH-012
225	20-BH-014

No.	Product Code
226	20-BH-016
227	20-BH-018
228	20-BH-020
229	20-IH-008
230	20-IH-010
231	20-IH-012
232	20-IH-014
233	20-IH-016
234	20-IH-018
235	20-IH-020
236	20L-AT-004
237	20L-AT-005
238	20L-AT-006
239	20L-AT-008
240	20L-AT-010
241	20L-AT-012
242	20L-MN-004
243	20L-MN-005
244	20L-MN-006
245	20L-MN-008
246	20L-MN-010
247	20L-MN-012
248	20L-MN-014
249	20L-MN-016
250	20L-MN-018
251	20-MN-004
252	20-MN-004A
253	20-MN-005
254	20-MN-005A
255	20-MN-006
256	20-MN-006A
257	20-MN-008
258	20-MN-008A
259	20-MN-010
260	20-MN-012
261	20-MN-014

No.	Product Code
262	20-MN-016
263	20-MN-018
264	20-MN-020
265	23L-MN-006
266	23L-MN-008
267	23L-MN-010
268	23L-MN-012
269	23L-MN-014
270	23L-MN-016
271	23-MN-004
272	23-MN-004A
273	23-MN-005
274	23-MN-005A
275	23-MN-006
276	23-MN-006A
277	23-MN-008
278	24-BH-008
279	24-BH-010
280	24-BH-012
281	24-BH-014
282	24-BH-016
283	24-BH-018
284	24-BH-020
285	24-IH-008
286	24-IH-010
287	24-IH-012
288	24-IH-014
289	24-IH-016
290	24-IH-018
291	24-IH-020
292	24L-AT-004
293	24L-AT-006
294	24L-AT-008
295	24L-MX-004
296	24L-MX-005
297	24L-MX-006

No.	Product Code
298	24L-MX-008
299	24L-MX-010
300	24L-MX-012
301	24L-MX-014
302	24L-MX-016
303	24L-MX-018
304	24-MX-004
305	24-MX-006
306	24-MX-008
307	24-MX-010
308	24-MX-012
309	24-MX-014
310	24-MX-016
311	24-MX-018
312	24-MX-020
313	27L-MX-006

No.	Product Code
314	27L-MX-008
315	27L-MX-010
316	27L-MX-012
317	27L-MX-014
318	27L-MX-016
319	27-MX-006
320	27-MX-008
321	27-MX-010
322	27-MX-012
323	20-AH-008
324	20-AH-010
325	20-AH-012
326	20-AH-014
327	20-AH-016
328	20-AH-018
329	20-AH-020

No.	Product Code
330	14-AH-006
331	14-AH-008
332	24-AH-008
333	24-AH-010
334	24-AH-012
335	24-AH-014
336	24-AH-016
337	24-AH-018
338	24-AH-020

List of Products with Class IIa

—Drill bit

No.	Product Code
1	112-MC-201
2	112-MC-202
3	112-MC-203
4	112-MC-204
5	112-MC-211
6	122-MC-301
7	112-MC-302
8	112-MC-401
9	112-MC-401-S
10	112-MC-511
11	112-MC-512
12	112-MC-STOP
13	112-MD-201
14	112-MD-301
15	112-MD-302
16	112-MD-401
17	112-MD-401-S
18	112-MD-511

No.	Product Code
19	112-MD-512
20	112-MD-STOP
21	112-MN-201
22	112-MN-202
23	112-MN-211
24	112-MN-301
25	112-MN-302
26	112-MN-303
27	112-MN-306
28	112-MN-401
29	112-MN-401-S
30	112-MN-511
31	112-MN-512
32	112-MN-STOP
33	112-MX-201
34	112-MX-202
35	112-MX-301
36	112-MX-302

No.	Product Code
37	112-MX-401
38	112-MX-401-S
39	112-MU-301
40	112-MU-302
41	112-MC-STOP06
42	112-MC-STOP08
43	112-MC-STOP10
44	112-MC-STOP12
45	112-MD-STOP10
46	112-MD-STOP12
47	112-MN-STOP08
48	112-MN-STOP10
49	112-MN-STOP12
50	112-MX-STOP06
51	112-MX-STOP08
52	112-MX-STOP10

List of Products with Class Im

—Depth Gauge

No.	Product Code
1	111-027
2	111-028

List of Products with Class I

—Surgical Instrument

No.	Product Code
1	113-MC-101
2	113-MC-102
3	113-MC-202
4	113-MC-203
5	113-MC-401
6	113-MC-511
7	113-MD-101
8	113-MD-201
9	113-MD-211
10	113-MD-401
11	113-MD-511
12	113-MN-101
13	113-MN-102
14	113-MN-201
15	113-MN-211
16	113-MN-401
17	113-MN-511
18	113-MX-101
19	113-MX-401
20	113-NF-101
21	113-MJ-103
22	113-MJ-104
23	113-MJ-105
24	113-MJ-202
25	113-MJ-203
26	113-MJ-204
27	113-MJ-205
28	113-MC-501
29	113-MD-501
30	113-MN-501
31	113-MX-501

No.	Product Code
32	113-NF-501
33	111-010
34	111-026-1
35	111-025R
36	111-025L
37	111-026-4
38	111-026-3
39	111-026-2
40	BD-05
41	111-023
42	DP-96
43	LX-103
44	DP-91
45	111-036
46	111-034
47	111-033
48	111-039
49	111-031
50	111-032
51	111-037
52	111-038
53	111-035L
54	111-035R
55	Channel Retractor
56	LINGUAL SPLITTER-R
57	LINGUAL SPLITTER-L
58	ARGRT
59	ARGLT
60	MRF-RTA
61	MRF-LTA
62	MRF-SYM

No.	Product Code
63	111-040
64	BANDAGE-S
65	BANDAGE-M
66	BANDAGE-L
67	12-QD-001
68	16-QD-001
69	20-QD-001
70	24-QD-001
71	111-043
72	111-042
73	111-050
74	111-050-1
75	111-052
76	111-053
77	111-041
78	111-045
79	111-051
80	111-048
81	111-076-M1
82	111-076-M2
83	111-076-M3
84	111-076-M4
85	111-076-OR
86	909.01HB01
87	909.01HB02
88	909.24PB01
89	111-026-1-L
90	111-026-2-L
91	111-026-3-L
92	111-026-4-L
93	114-007

No.	Product Code
94	114-008
95	114-009
96	111-023-1
97	909.24PB02
98	111-041-1
99	24-AE-004TP
100	24-AE-006TP
101	24-AE-104TP
102	24-AR-015TP
103	24-CD-006TP
104	24-RM-025TP
105	24-RR-020TP
106	24-RS-015TP
107	24-RS-021TP
108	24-RS-025TP
109	24-SB-004TP
110	24-SB-007TP
111	24-SB-008TP
112	24-SB-104TP
113	24-SB-204TP
114	24-SE-004TP
115	24-SE-006TP
116	24-SE-104TP
117	24-ST-004TP
118	24-ST-006TP
119	24-ST-104TP
120	242.60RS15TP
121	242.60RS21TP
122	242.60RS25TP
123	242.6xRS21.xxTP
124	242.60RL/RR14TP
125	242.60RL/RR19TP
126	242.6xRL/RR16.xxTP
127	242.6xRL/RR18.xxTP
128	242.60RM23TP
129	242.6xRM23.xxTP

No.	Product Code
130	242.6xRM25.xxTP
131	242.50LL/LR06TP
132	242.51LL/LR06TP
133	242.52LL/LR06TP
134	242.53LL/LR06TP
135	242.50LL/LR16TP
136	242.51LL/LR16TP
137	242.52LL/LR16TP
138	242.53LL/LR16TP
139	242.50DR06TP
140	242.51DR06TP
141	242.52DR06TP
142	242.53DR06TP
143	242.50DR16TP
144	242.51DR16TP
145	242.52DR16TP
146	242.53DR16TP
147	242.50SP06.01TP
148	242.51SP06.01TP
149	242.52SP06.01TP
150	242.53SP06.01TP
151	242.54SP06.01TP
152	242.55SP06.01TP
153	242.56SP06.01TP
154	242.50SP16.01TP
155	242.51SP16.01TP
156	242.52SP16.01TP
157	242.53SP16.01TP
158	242.54SP16.01TP
159	242.55SP16.01TP
160	242.56SP16.01TP
161	242.57SP16.01TP
162	242.5xTPxx.01TP
163	242.51CH13TP
164	242.52CH13TP
165	242.53CH13TP

No.	Product Code
166	242.54CH13TP
167	242.55CH13TP
168	242.56CH13TP
169	242.57CH13TP
170	242.58CH13TP
171	242.50YL/YR08.B0TP
172	242.50YL/YR08.B3TP
173	242.50YL/YR08.B5TP
174	242.50YL/YR08.B7TP
175	242.50YL/YR08.B10TP
176	242.50YL/YR08.B15TP
177	242.50YL/YR08.B20TP
178	242.50SQ04.02TP
179	242.50QD06.02TP
180	242.50QD08.02TP
181	111-021
182	111-051-L1
183	111-051-L2
184	111-076-OR-S
185	111-076-OR-L
186	111-158
187	111-158-T
188	111-158-F
189	111-026-1-N
190	111-026-2-N
191	111-026-3-N
192	111-026-4-N
193	111-051-P
194	111-010LA
195	111-001
196	111-003
197	111-004
198	111-005
199	111-006
200	111-007
201	111-008

No.	Product Code
202	111-009
203	111-011
204	111-012
205	111-013
206	111-016
207	111-017
208	111-018
209	111-019
210	911.24AS01
211	911.24SCA1.01
212	911.24SCA2.01
213	911.24AS02
214	911.24SCA3.01
215	911.24AS03
216	911.24AS04
217	911.24AS05
218	911.24AS06
219	911.24AS07

No.	Product Code
220	911.24AS08
221	912.24AS01
222	912.24AS02
223	912.24AS03
224	912.24AS04
225	912.24AS05
226	910.24AS01
227	910.24AS02
228	910.24AS03
229	910.24AS04
230	910.24AS05
231	111-014-1
232	111-014-2
233	111-015-1
234	111-015-2
235	911.24AS04.01
236	910.24AS04.01
237	910.24AS05.01

No.	Product Code
238	910.24AS06
239	911.24AS10
240	911.24AS09
241	911.24SCA5
242	911.24SCA6
243	913.24MT01
244	913.24MT02
245	913.24MT03
246	913.24MT04
247	111-009LA
248	111-009LA_Container
249	111-005LA
250	111-013LA
251	111-006LA
252	111-007LA
253	111-006-L
254	111-014LA
255	912.24AS06

Addendum to Declaration of Conformity (DoC)

Issue Date: 2024-05-22

This addendum to Declaration of Conformity is effective as of the date last issued and is subject to the below device.

- Subject: TCF01-1 (Rev. 1, Issue Date: 2020-03-05)

By this addendum, we, Jeil Medical Corporation, as the manufacturer agree to the change as below.

[Changes]

No.	Description	Effective Date
1	<u>Address change of Authorized Representative (AR)</u> - Address of EMERGO EUROPE mentioned on existed pages 1 to 4 was changed as below. • (Before) Prinsessegracht 20, 2514 AP, The Hague, The Netherlands • (After) Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands	2023-01-31
2	<u>Deletion of page 5</u> - Existed page 5 in DoC related to devices classified as Class III pursuant to the Canadian Medical Device Regulations (SOR/98-282) was excluded.	2024-03-07
3	<u>Deletion of models that did not transition to the MDR</u> - Existed pages 2 to 4 in DoC related to devices classified as Class I, Class Im and Class IIa pursuant to the Medical Device Directive (93/42/EEC) was excluded. - Due to the expiration of the Medical Device Directive (93/42/EEC), models that were not transitioned to the Medical Device Regulation (2017/745) have been excluded. <u>Postal code change of Manufacturer</u> - Postal code of Manufacturer mentioned on existed page 1 was changed as below. • (Before) 152-728 • (After) 08378	2024-05-26



Sejin Ryu

Seoul, Korea / May 22nd, 2024

Person Responsible for Regulatory Compliance

Jeil Medical Corporation