

Date: 19 April 2022

To whom may concern

We, **Furuno Electric Co., Ltd.** located in 2-20 Nishinomiyahama, Nishinomiya, Hyogo, 662-0934, Japan; as product owner, hereby declares that the medical devices mentioned in Attachment 1 comply to the below standard.

List of Standards Applied:

EN ISO 13485:2016 Medical devices - Quality management systems –
Requirements for regulatory purposes (ISO 13485:2016)

Signature:



Name: Kenji Kitagawa

Position: General Manager, Sales Section, Sales Department 3, System Products Division

For and on behalf of Furuno Electric Co., Ltd.

Attachment 1

No	Item Code	Item Name
1	003B4014700	Etching
2	003B4014800	Diluent
3	003B4034800	ISE Cleaner
4	003B4014300	L Solution
5	003B4014400	Ref Solution
6	003B4014500	H Solution
7	003B4015000	Ref Electrode
8	003B4015100	Na Electrode
9	003B4015200	K Electrode
10	003B4015300	Cl Electrode
11	00003592200	BUFFER SOLUTION
12	00003592500	DETERGENT SOLUTION
13	00003592000	INTERNAL STANDARD 200ML
14	00003592300	SERUM STANDARD SET
15	00003592400	URINE STANDARD SET
16	00003592600	NA/K CHECK SOLUTION
17	00003591600	NA ELECTRODE
18	00003591700	K ELECTRODE
19	00003591800	CL ELECTRODE
20	00003591900	REF ELECTRODE