2 022 EBC Remarks by the Chairman of the Board of Representatives

This is Mr. Mori, the chairperson. Thank you very much for taking the time out of your busy schedule to attend the meeting of representatives of the Medical Devices IVD Committee.

Over the past year, in addition to the coronavirus crisis, various problems have come to Japan, including the issues of Russia and Ukraine, natural disasters such as earthquakes and heavy rain, and missile launches from North Korea. Costs have risen in various ways due to a shortage of semiconductors, a shortage of raw materials and usual materials, a shortage of human resources, and the impact of the depreciation of the yen. Even though we in the medical device industry have not been able to pass on costs to customers, we have made efforts to contribute to system reform through stable supply, provision of medical care in times of disaster, and medical care DX.

In addition, amidst similar turmoil around the world, Japan has made various efforts to bring as much as possible necessary items, such as coronavirus antigen test kits, to Japan.

Under such circumstances, through the activities of the Committee, we have been able to continue to make policy proposals, to promote deregulation, to make proposals on medical treatment fees, and to strengthen relations with related organizations as you have seen. This is due to the understanding of you and the efforts of the member companies who have actually made such efforts. Thank you again.

2022 is the third year of the revision of the Pharmaceutical and Medical Devices Law in 2020 and also the year of completion. This month's UDI, "Obligation to Display Barcodes on Packages, etc.", has implemented all of these regulations. In addition, the Challenge Application became available in an expanded manner, and it was also the year when the full-scale implementation of MDSAP started.

Further studies on programmed medical devices are ongoing and discussions are being held regarding their applicability and evaluation methods. Various proposals have also been made on how to ensure the predictability of insurance.

This summer, we invited all of you for the first time in three years, invited Minister of Health, Labour and Welfare Katoh and Professor Mano to the venue of the Europa House of the European Union to Japan, and gave a lecture on medical

DXs. I was also pleased to have a lively information exchange meeting with you on F2F for the first time in a long time.

There are still many issues to be addressed, but I think it was a fruitful year.

Now 2023 As you can see, we must continue to work on many of the issues that we should work on during the fiscal year.

Among them, cyber security for medical institutions that has been in the news recently, revision of the Infectious Diseases Law, provisional approval system for programmed medical devices with insurance, C2 challenge, and even bigger, who are in-vitro diagnostics? We must establish the basic standing position of IVD and create a foundation that can solve the unclear problems so far.

Also, since we are a European company, it is a very important activity to increase our presence to send various European information including DiGA to Japan.

Following on from last year, DiGA webinars have generated a great response this year. Thank you very much.

In addition, 2023 year is Reiwa 6 year (2024 year) is the year of preparation for the medical fee revision, and it is expected that our corporate activities in the future will produce very significant results. I believe that there will be more and more expectations for the activities of this Committee in the future, but I would

like to ask the members to continue to be active, and more importantly, I would like to ask for the understanding of the company representatives and their high evaluation.

In that case, I would like to wish each of you all good luck and report to you.

Thank you very much for today. We also ask you to attend the Information Exchanging after the meeting.

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