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Notice Regarding Voluntary Product Recall of "MANI DIA-BURS" in China

MANI, INC. hereby announces that the Company resolved to conduct a voluntary recall of "MANI DIA-BURS (Generic name is Dental Diamond Burs)" in China.

We sincerely apologize for any inconvenience and concern this may cause to all parties involved.

1. Outline and Background of the Voluntary Recall

Regarding the "MANI DIA-BURS (Generic name is Dental Diamond Burs)" that the Company manufactures and sells, it was found that part of the product registration information submitted to the Chinese regulatory authorities was incomplete. Therefore, we have decided to conduct a voluntary recall of the products in question. The Company has determined that there are no problems with the quality, efficacy, or safety of the product and that there is no risk of harm to patients' health.

The voluntary recall is a matter to be reported to the Chinese regulatory authorities and will not affect sales in other regions.

(Overview of Product Subject to Voluntary Recall)

① Product subject to recall: MANI DIA-BURS (Registration number: Guo Xie Zhu Jin 20152172079)
② Country subject to recall: China

2. Future Sales Outlook

Following this decision, the Company is currently recalling the products in question and applying for changes to correct the incomplete information. Approximately 50% of the "MANI DIA-BURS" will require changes to their product registration information, and sales of these products will be suspended until the application for changes is certified. As for other products, we will take appropriate measures and continue to sell them. In addition, the annual sales of MANI DIA-BURS in China are approximately ¥2.5 billion (actual sales results for the fiscal year ended August 31, 2024).

3. Future Outlook

The impact on the consolidated financial results for the fiscal year ending August 31, 2025, is currently under close examination, and if any matters arise that should be announced in the future, we will disclose them promptly.

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