[Form 2]

Date of application: / /

To the Japan Breath Alcohol Testing Consortium

Breath Alcohol Detector Examination Application Form

Breath Alcohol Detector J-BAC Mark System Examination (Model Certification)

Conformity Statement

○Rule about Alcohol Breathalyzer Marketing Guidelines

I hereby confirm that I satisfy the following requirements about accountability through catalogs and operating instructions as specified in the main document, Chapter 2, **2.2.** (The following items shall be all included in the instruction manual.)

No.	Content	Where it is written
1)	The Road Traffic Act, Article 65, Paragraph 1 stipulates the rule that it is prohibited for any person to drive a vehicle or streetcar while under the influence of alcohol. The data from the device is only a guide to detect alcohol drinking and not to authorize or prohibit driving. The manufacturer and parties involved in distribution of the device are not liable for determination of whether to allow driving a vehicle or manipulation of equipment based on the measurement result. Whether such information is provided.	
2)	The sensor of breath alcohol detector will not work permanently but becomes deteriorated while it is used. - Whether such information is provided.	
3)	Whether the number of times of use and the lifetime after purchase are provided.	
4)	Whether the restrictions of use and storage environments (indoor, outdoor, cold, hot, temperature, humidity, etc.) are provided.	
5)	Whether repair, maintenance, and calibration after purchase is explained.	
6)	Whether the impact of the power supply voltage fluctuation on the performance, if any, is explained.	
7)	Whether how to breath is explained.	
8)	Whether the instruments (a straw, mouthpiece, etc.) used to measure breath are explained.	
9)	Whether the measurement unit (mg/L) is explained.	
10)	Whether the measurement range (including the definition of 0.000 and the masking range) is explained.	
11)	Whether appropriate descriptions about residual gas are provided. (intervals, recovery time, etc.)	
12)	Whether retention of the measurement record is explained.	
13)	Whether substances other than those measured (interference components) are explained.	
14)	Whether actions in case of detecting substances other than those measured (interference components) are explained.	

○Quality Assurance System

The following information shall be summarized and provided in relation to the main document, Chapter 2, **2.3 Requirements about the Quality Assurance System**.

No.	Item	Summary
1	Manufacture of the device	[Model name] Example: AAA-00001 [Origin] (for initial and surveillance audits) Example: Japan, China, etc. [Final testing (shipping inspection) site] (for initial and surveillance audits) Example: XX factory in XX prefecture, XX testing center in XX prefecture [ISO certification, etc.] (distributor, important intermediate processes, final testing site, etc.) Example: ISO9001 certified Example: Not ISO certified but adhering to the internal assurance system, etc.
2	Identification and Traceability	[Unique product identification] Example: A manufacturing number (serial number) is assigned and displayed on each product. A manufacturing number provides traceability by indicating the time of manufacture, time of final testing, place of manufacture, and software version.
3	Controlling the Monitoring and Measuring Instruments	[Explanation of testing equipment and materials] Example: An internally manufactured air compressor and a Guth's simulator are used. An alcohol solution of a prescribed concentration is procured. The frequency of using an alcohol solution in the simulator is controlled in accordance with the internal instructions for replacing the solution in the simulator. The Guth's simulator is calibrated by the manufacturer.
4	Monitoring and Measuring the Product	[Receiving inspection and testing] Example: Manufacture of the product is partially outsourced. An electrical method is used for receiving inspection. [In-process inspection and testing] Example: Processes are inspected in accordance with their respective manuals. [Inspection and final testing] Example: The final alcohol detection precision check is also outsourced and the product is accepted by checking the inspection record.
5	Controlling Non-conforming Products	[Elimination] Example: Non-conforming products detected in the process are disposed of. [Exceptional acceptance] Example: If non-conforming products detected in the process of manufacturing are accepted through design modification, the document of exceptional acceptance is internally issued and then the products are delivered to the market. [Collection] Example: Non-conforming products already in the market shall be immediately collected after notification to the customer.