

| <b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b><br><b>FOOD AND DRUG ADMINISTRATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |                                                                       |                                                                                                                                                                                                                                                                                                                               |
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| <small>DISTRICT ADDRESS AND PHONE NUMBER</small><br>158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax: (718) 662-5661                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                               | <small>DATE(S) OF INSPECTION</small><br>10/15/2025-10/20/2025*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |                                                                       |                                                                                                                                                                                                                                                                                                                               |
| <small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small><br>Corinne Masto, V.P. of Service Excellence                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                               | <small>FEI NUMBER</small><br>2430101                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  |                                                                       |                                                                                                                                                                                                                                                                                                                               |
| <small>FIRM NAME</small><br>WS Audiology USA Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                               | <small>STREET ADDRESS</small><br>185 Commerce Dr                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |                                                                       |                                                                                                                                                                                                                                                                                                                               |
| <small>CITY, STATE, ZIP CODE, COUNTRY</small><br>Hauppauge, NY 11788-3916                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                               | <small>TYPE ESTABLISHMENT INSPECTED</small><br>Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |                                                                       |                                                                                                                                                                                                                                                                                                                               |
| <p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |                                                                       |                                                                                                                                                                                                                                                                                                                               |
| <p><i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |                                                                       |                                                                                                                                                                                                                                                                                                                               |
| <p><b>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</b><br/> <b>OBSERVATION 1</b><br/>           Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.</p> <p>Specifically, your firm's complaint handling procedure entitled Complaint Handling, Doc. ID GLOBAL_SOP_QM_004 Version 14 dated 2/15/2025 does not include adequately written instructions that specify how employees are required to investigate and document complaints. More specifically, this procedure does not list all of your firm's internal records that should be considered for review during a complaint investigation, nor does it include instructions to document the results of these internal record investigations in your firm's complaint records. For example, device history records which document production conditions and finished device acceptance test results, or internal receiving inspection test results for materials used to manufacture devices.</p> |                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |                                                                       |                                                                                                                                                                                                                                                                                                                               |
| <p><b>*DATES OF INSPECTION</b><br/>           10/15/2025(Wed), 10/16/2025(Thu), 10/17/2025(Fri), 10/20/2025(Mon)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |                                                                       |                                                                                                                                                                                                                                                                                                                               |
| <b>SEE REVERSE OF THIS PAGE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                               | <table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small><br/>           Andrew J Garufi, Investigator         </td> <td style="width: 40%; vertical-align: top;"> <div style="text-align: right;"> <small>DATE ISSUED</small><br/>           10/20/2025         </div> <div style="text-align: right; margin-top: 20px;"> <small>Andrew J Garufi<br/>           Investigator<br/>           Signed By: 2001292217<br/>           Date Signed: 10-20-2025<br/>           14:33:08</small> </div> </td> </tr> </table> |  | <small>EMPLOYEE(S) SIGNATURE</small><br>Andrew J Garufi, Investigator | <div style="text-align: right;"> <small>DATE ISSUED</small><br/>           10/20/2025         </div> <div style="text-align: right; margin-top: 20px;"> <small>Andrew J Garufi<br/>           Investigator<br/>           Signed By: 2001292217<br/>           Date Signed: 10-20-2025<br/>           14:33:08</small> </div> |
| <small>EMPLOYEE(S) SIGNATURE</small><br>Andrew J Garufi, Investigator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <div style="text-align: right;"> <small>DATE ISSUED</small><br/>           10/20/2025         </div> <div style="text-align: right; margin-top: 20px;"> <small>Andrew J Garufi<br/>           Investigator<br/>           Signed By: 2001292217<br/>           Date Signed: 10-20-2025<br/>           14:33:08</small> </div> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |                                                                       |                                                                                                                                                                                                                                                                                                                               |

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|--------------------------------------------|------------------------|
| DISTRICT ADDRESS AND PHONE NUMBER          | DATE(S) OF INSPECTION  |
| 158-15 Liberty Avenue                      | 10/15/2025-10/20/2025* |
| Jamaica, NY 11433                          | FEI NUMBER             |
| (718) 340-7000 Ext:5301 Fax:(718) 662-5661 | 2430101                |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Corinne Masto, V.P. of Service Excellence

|                       |                 |
|-----------------------|-----------------|
| FIRM NAME             | STREET ADDRESS  |
| WS Audiology USA Inc. | 185 Commerce Dr |

|                                |                              |
|--------------------------------|------------------------------|
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Hauppauge, NY 11788-3916       | Manufacturer                 |

Observation 1:

DATE ISSUED  
10/20/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."