

## DECLARATION DE CONFORMITÉ

### DECLARATION OF CE CONFORMITY

Cette déclaration a pour but de garantir que nous :  
 This declaration is intended to ensure that we:

COMED SAS  
 PARC DES FORGES - 8 Rue Louise Michel  
 67200 STRASBOURG  
 FRANCE

déclarons, sous notre seule responsabilité, que le dispositif :  
 declare, under our sole responsibility, that the device:

### SPECULUMS AURICULAIRES A USAGE UNIQUE DISPOSABLE EAR SPECULUMS

n° de référence du Dispositif Médical :  
 item numbers of the Medical Devices:

|             |             |              |            |            |
|-------------|-------------|--------------|------------|------------|
| 2470025AX   | 2470040AX   | 2470125BS    | 2471025AX  | 2472025AX  |
| 2470025BS   | 2470040BS   | 2470125/125B | 2471025BS  | 2472025BS  |
| 2470025AC   | 2470040AC   | 2470125V     | 2471025AGI | 2472025AGI |
| 2470025ADCM | 2470040ADCM | 2470125BGI   |            |            |
| 2470025ACAP | 2470040ACAP |              |            |            |
| 2470025AXRO | 2470040AXRO |              |            |            |
| 2470025BSD  | 2470040BSD  |              |            |            |
| 2470025BCBD | 2470040BCBD |              |            |            |
| 2470025BCJD | 2470040BCJD |              |            |            |
| 2470025BCRD | 2470040BCRD |              |            |            |
| 2470025BCVD | 2470040BCVD | 2470140BS    | 2471040AX  | 2472040AX  |
| 2470025APR  | 2470040APR  | 2470140/125B | 2471040BS  | 2472040BS  |
| 2470025BCB  | 2470040BCB  | 2470140V     | 2471040AGI | 2472040AGI |
| 2470025BSM  | 2470040BSM  | 2470140BGI   |            |            |
| 2470025BCBM | 2470040BCBM |              |            |            |
| 2470025BCJM | 2470040BCJM |              |            |            |
| 2470025BCRM | 2470040BCRM |              |            |            |
| 2470025BCVM | 2470040BCVM |              |            |            |
| 2470025LUX  | 2470040BCN  |              |            |            |
| 2470025ADOC | 2470040LUX  |              |            |            |
|             | 2470040ADOC |              |            |            |

appartenant à la Classe I en application de la règle 5 de l'annexe IX de la Directive européenne 93/42/CEE,

*belonging to Class I according to Rule 5 of Annex IX of the European Directive 93/42/EEC,*

est conforme aux exigences applicables de la directive 93/42/CEE et satisfait également aux dispositions des articles L.5211-1 et R-5211-39 du Livre V du Code de la Santé Publique français qui lui sont applicables.

*complies with the applicable requirements of Directive 93/42/EEC and also complies with Articles L.5211-1 and R-5211-39 of Book V of the French Public Health Code which apply to it.*

Cette déclaration est basée sur :

*This statement is based on:*

- le dossier technique DT01 v4 démontrant la conformité aux exigences essentielles de la directive 93/42/CEE  
*technical file DT01 v4 demonstrating compliance with the essential requirements of Directive 93/42/EEC*
- l'annexe VII de la directive 93/42/CEE  
*annex VII of Directive 93/42/EEC*

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**Annabel JAEGEL-GASTINE**  
 Directrice Générale / General Manager  
 Responsable Qualité / Quality Manager

