

**DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE**

**Validity declaration of conformity from date / Date de déclaration de conformité :**

**Place / Lieu d'émission :**

Marcy l'Etoile - FRANCE

**Date of the issue of the declaration of conformity / Date d'application de la déclaration de conformité :**

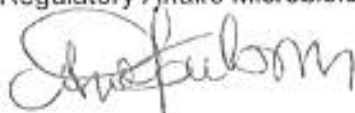
26-NOV-2019

**Name - Title / Nom - Fonction :**

Asa KARLSSON

Sr. Manager, Regulatory Affairs Microbiology Unit

**Signature :**



**Product identification / Identification du produit :**

ETEST®

See attached list / Voir liste ci-jointe

**Identification of the person who has the power of attorney to bind the manufacturer / Nom et qualité de la personne engageant la responsabilité du fabricant :**

**Name / Nom :**

Manuela KAUL

**Title / Fonction :**

VP Global Clinical & Regulatory Affairs

**Identification of the legal entity / Identification de l'entité légale :**

**Manufacturer / Fabricant :**

**Name / Nom :**

BIOMERIEUX SA

**Address / Adresse :**

376 Chemin de l'Orme 69280 Marcy-l'Etoile -  
FRANCE

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« We, the manufacturer declare that the above mentioned products comply with the Directives and their relevant implementations into all national laws of the member states into which we place the products » / « Nous, fabricant, déclarons que les produits mentionnés ci-dessus satisfont aux Directives et leurs transpositions en droit national dans les Etats Membres dans lesquels les produits sont mis sur le marché. »

**Conformity assessment procedure used to demonstrate compliance / Procédure d'évaluation de conformité choisie :**

Annex / Annexe (s) : Annex III (section 6 excluded) / Annexe III (section 6 exclue)

Directive (s) : 98/79/CE

**Device classification / Classification du dispositif :**

Directive 98/79/CE : ☐ List(e) A, Annex(e) II ☐ List(e) B, Annex(e) II ☒ Other / Autre ☐ Self-testing / Autotest



## DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

| PRODUCT NAME                                       | CODE ON STRIP | MIC (µg/mL)      | FOAM PACK. REF. NO. | BUSTER PACK. REF. NO. | SINGLE PACK. REF. NO. |
|----------------------------------------------------|---------------|------------------|---------------------|-----------------------|-----------------------|
| <b>ETEST for Antibiotic Susceptibility Testing</b> |               |                  |                     |                       |                       |
| Ettest® Amikacin                                   | AK            | 0.016-256        | 501318              | -                     | 412219                |
| Ettest® Amoxicillin                                | AC            | 0.016-256        | 500918              | -                     | 412243                |
| Ettest® Amoxicillin/clavulanic acid (3/1)          | BL            | 0.016-256        | 501018              | -                     | 412241                |
| Ettest® Ampicillin                                 | AM            | 0.016-256        | 501518              | -                     | 412253                |
| Ettest® Ampicillin/sulbactam (2/1)                 | AB            | 0.016-256        | 501818              | -                     | 412251                |
| Ettest® Azithromycin                               | AZ            | 0.016-256        | 501618              | -                     | 412257                |
| Ettest® Aztreonam                                  | AT            | 0.016-256        | 501718              | -                     | 412259                |
| Ettest® Bacitracin                                 | BA            | 0.016-256        | -                   | 528600                | -                     |
| Ettest® Benzylpenicillin                           | PG            | 0.016-256 (high) | 502518              | -                     | 412263                |
| Ettest® Benzylpenicillin                           | PG            | 0.002-32 (low)   | 502618              | -                     | 412265                |
| Ettest® Cefadiazole                                | CF            | 0.016-256        | -                   | -                     | 412271                |
| Ettest® Cefepime                                   | PM            | 0.016-256        | 505018              | -                     | 412273                |
| Ettest® Cefixime                                   | X             | 0.016-256        | 529918              | -                     | 412275                |
| Ettest® Cefotaxime                                 | CT            | 0.016-256 (high) | 505518              | -                     | 412279                |
| Ettest® Cefotaxime                                 | CT            | 0.002-32 (low)   | 505618              | -                     | 412281                |
| Ettest® Cefotetan                                  | DN            | 0.016-256        | -                   | 506308                | -                     |
| Ettest® Cefotetan                                  | DN            | 0.016-256        | -                   | 506300                | -                     |
| Ettest® Cefazolin                                  | FX            | 0.016-256        | 506518              | -                     | 412285                |
| Ettest® Cefprozil                                  | FX            | 0.016-256        | 506818              | -                     | 412289                |
| Ettest® Ceftazidime                                | CPT           | 0.002-32         | -                   | 537500                | -                     |
| Ettest® Ceftazidime                                | TZ            | 0.016-256        | 506718              | -                     | 412293                |



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|-----------------------------------------|---------------|-------------|--------|---------------------|------------------------|-----------------------|
| Etest® Ceftazidime/ Avibactam (4 µg/mL) | CEA           | 0.016 - 256 |        | -                   | -                      | 419556                |
| Etest® Ceftriaxone/ Tobactam (4 µg/mL)  | C/T           | 0.016 - 256 |        | -                   | -                      | 414447                |
| Etest® Ceftriaxone                      | TX            | 0.016-256   | (high) | 506618              | -                      | 412301                |
| Etest® Ceftriaxone                      | TX            | 0.002-32    | (low)  | 507018              | -                      | 412303                |
| Etest® Cefuroxime                       | XM            | 0.016-256   |        | 506918              | -                      | 412305                |
| Etest® Cephalothin                      | CE            | 0.016-256   |        | -                   | -                      | 412307                |
| Etest® Chloramphenicol                  | CL            | 0.016-256   |        | 507518              | -                      | 412308                |
| Etest® Ciprofloxacin                    | CI            | 0.002-32    |        | 508918              | -                      | 412311                |
| Etest® Clarithromycin                   | CH            | 0.016-256   |        | 508718              | -                      | 412313                |
| Etest® Clindamycin                      | CM            | 0.016-256   |        | 509518              | -                      | 412315                |
| Etest® Colistin                         | CO            | 0.016-256   |        | -                   | 517303                 | -                     |
| Etest® Colistin                         | CO            | 0.016-256   |        | -                   | 517300                 | -                     |
| Etest® Daptomycin                       | DPC           | 0.016-256   |        | 535918              | -                      | 412324                |
| Etest® Daptomycin                       | DOR           | 0.002-32    |        | 535918              | -                      | 412326                |
| Etest® Doxycycline                      | DC            | 0.016-256   |        | 508718              | -                      | 412328                |
| Etest® Enrofloxacin                     | EF            | 0.002-32    |        | -                   | 516900                 | -                     |
| Etest® Entapenem                        | ETP           | 0.002-32    |        | -                   | -                      | 412332                |
| Etest® Entapenem                        | ETP           | 0.002-32    |        | -                   | 516900                 | -                     |
| Etest® Erythromycin                     | EM            | 0.016-256   |        | 510518              | -                      | 412334                |
| Etest® Fosfomycin                       | FM            | 0.054-1024  |        | -                   | 529108                 | -                     |
| Etest® Fosfomycin                       | FM            | 0.054-1024  |        | -                   | 529100                 | -                     |
| Etest® Fusidic acid                     | FU            | 0.016-256   |        | -                   | 511508                 | -                     |
| Etest® Fusidic acid                     | FU            | 0.016-256   |        | 511520              | -                      | -                     |
| Etest® Garosilacin                      | GA            | 0.002-32    |        | -                   | -                      | 412352                |



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|-----------------------|---------------|-------------|--------|-------------------|---------------------|---------------------|
| Etest® Gentamicin     | GM            | 0.064-1024  | (High) | -                 | 512708              | -                   |
| Etest® Gentamicin     | GM            | 0.064-1024  | (High) | -                 | 512700              | -                   |
| Etest® Gentamicin     | GM            | 0.016-256   | (Low)  | 512518            | -                   | 412368              |
| Etest® Imipenem       | IP            | 0.002-32    |        | 513618            | -                   | 412374              |
| Etest® Kanamycin      | KM            | 0.016-256   |        | 527818            | -                   | 412382              |
| Etest® Levofloxacin   | LE            | 0.002-32    |        | 527418            | -                   | 412393              |
| Etest® Linezolid      | LZ            | 0.016-256   |        | 531518            | -                   | 412395              |
| Etest® Meropenem      | MP            | 0.016-256   |        | -                 | 513700              | -                   |
| Etest® Meropenem      | MP            | 0.002-32    |        | -                 | 513808              | 412402              |
| Etest® Meropenem      | MP            | 0.002-32    |        | -                 | 513800              | -                   |
| Etest® Meropenem      | MZ            | 0.016-256   |        | 530018            | -                   | 412404              |
| Etest® Minocycline    | MC            | 0.016-256   |        | 516018            | -                   | 412409              |
| Etest® Moxifloxacin   | MX            | 0.002-32    |        | 528018            | -                   | 412411              |
| Etest® Mupirocin      | MPJ           | 0.064-1024  |        | -                 | 516308              | -                   |
| Etest® Mupirocin      | MU            | 0.064-1024  |        | -                 | 516300              | -                   |
| Etest® Nalidixic acid | NA            | 0.016-256   |        | -                 | 516508              | -                   |
| Etest® Nalidixic acid | NA            | 0.016-256   |        | -                 | 516500              | -                   |
| Etest® Netilmicin     | NC            | 0.016-256   |        | 517518            | -                   | 412422              |
| Etest® Nitrofurantoin | NI            | 0.032-512   |        | -                 | 530408              | -                   |
| Etest® Nitrofurantoin | NI            | 0.032-512   |        | -                 | 530400              | -                   |
| Etest® Norfloxacin    | NX            | 0.016-256   |        | -                 | 519908              | -                   |
| Etest® norfloxacin    | NX            | 0.016-256   |        | -                 | 519900              | -                   |
| Etest® Ofloxacin      | OF            | 0.002-32    |        | -                 | 519508              | -                   |
| Etest® Ofloxacin      | OF            | 0.002-32    |        | 519610            | -                   | -                   |



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|----------------------------------------------|---------------------|-------------------|--------------------------|-----------------------------|----------------------------|
| Etest® Oxacillin                             | OX                  | 0.016-256         | 520518                   | -                           | 412432                     |
| Etest® Piperacillin                          | PP                  | 0.016-256         | 521518                   | -                           | 412436                     |
| Etest® Polymyxin B                           | PO                  | 0.064-1024        | -                        | 533403                      | -                          |
| Etest® Polymyxin B                           | PO                  | 0.064-1024        | -                        | 533402                      | -                          |
| Etest® Quinoloxon/difloxacin                 | QDA                 | 0.002-32          | 528718                   | 528708                      | -                          |
| Etest® Quinoloxon/difloxacin                 | QDA                 | 0.002-32          | 528710                   | 528700                      | -                          |
| Etest® Rifampicin                            | RI                  | 0.002-32          | 526013                   | -                           | 412450                     |
| Etest® Spectinomycin                         | SC                  | 0.064-1024        | 529218                   | -                           | 412452                     |
| Etest® Streptomycin                          | SM                  | 0.064-1024        | -                        | 526808                      | -                          |
| Etest® Streptomycin                          | SM                  | 0.064-1024        | -                        | 526820                      | -                          |
| Etest® Sulfamethoxazole                      | SK                  | 0.064-1024        | 534118                   | -                           | 412453                     |
| Etest® Teicoplanin                           | TP                  | 0.016-256         | 522018                   | -                           | 412461                     |
| Etest® Tetracycline                          | TC                  | 0.016-256         | 522518                   | -                           | 412471                     |
| Etest® Ticarcillin/clavulanic acid (2 µg/mL) | TLe                 | 0.016-256         | 522618                   | -                           | 412473                     |
| Etest® Tigecycline                           | TGC                 | 0.016-256         | -                        | 533508                      | 412475                     |
| Etest® Tigecycline                           | TGC                 | 0.016-256         | -                        | 533500                      | -                          |
| Etest® Tobramycin                            | TM                  | 0.064-1024 (high) | -                        | 533108                      | -                          |
| Etest® Tobramycin                            | TM                  | 0.064-1024 (high) | -                        | 533100                      | -                          |
| Etest® Tobramycin                            | TM                  | 0.016-256 (low)   | 522718                   | -                           | 412479                     |
| Etest® Trimethoprim                          | TR                  | 0.002-32          | 523618                   | -                           | 412483                     |
| Etest® Trimethoprim/sulfamethoxazole (1/19)  | TS                  | 0.002-32          | 524418                   | -                           | 412481                     |
| Etest® Vancomycin                            | VA                  | 0.016-256         | 525518                   | -                           | 412485                     |



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|---------------------------------------------|---------------------|-------------|--------------------------|-----------------------------|----------------------------|
| ETEST for Antifungal Susceptibility Testing |                     |             |                          |                             |                            |
| Etect® Amphotericin B                       | AP                  | 0.002-32    | 526318                   | 526308                      | 412249                     |
| Etect® Amphotericin B                       | AP                  | 0.002-32    | -                        | 526320                      | -                          |
| Etect® Anidulafungin                        | AND                 | 0.002-32    | -                        | 532008                      | -                          |
| Etect® Anidulafungin                        | AND                 | 0.002-32    | -                        | 532000                      | -                          |
| Etect® Caspofungin                          | CS                  | 0.002-32    | 532418                   | -                           | 412269                     |
| Etect® Fluconazole                          | FL                  | 0.016-256   | 510818                   | -                           | 412350                     |
| Etect® Fluconazole                          | FL                  | 0.002-32    | 510918                   | -                           | 412352                     |
| Etect® Itraconazole                         | IT                  | 0.002-32    | 525818                   | -                           | 412380                     |
| Etect® Itraconazole                         | KE                  | 0.002-32    | 525918                   | -                           | 412391                     |
| Etect® Micafungin                           | MYC                 | 0.002-32    | -                        | 535708                      | -                          |
| Etect® Micafungin                           | MYC                 | 0.002-32    | -                        | 535700                      | -                          |
| Etect® Posaconazole                         | POS                 | 0.002-32    | -                        | -                           | 412449                     |
| Etect® Posaconazole                         | POS                 | 0.002-32    | -                        | 532100                      | -                          |
| Etect® Voriconazole                         | VO                  | 0.002-32    | 531818                   | -                           | 412490                     |



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|--------------------------------------------------------------------------|---------------|------------------|-------------------|----------------------|---------------------|
| <b>ETEST ESBL for Confirmation of "Extended Spectrum Beta-Lactamase"</b> |               |                  |                   |                      |                     |
| Etest® Cefotaxime/cefotaxime + clavulanic acid (4 µg/mL)                 | CT/CTL        | 0.25-16/0.016-1  | -                 | 532208               | -                   |
| Etest® Cefotaxime/cefotaxime + clavulanic acid (8 µg/mL)                 | CT/CTL        | 0.25-16/0.016-1  | -                 | 532290               | -                   |
| Etest® Ceftazidime/ceftazidime + clavulanic acid (4 µg/mL)               | TZ/TZL        | 0.5-32/0.064-4   | -                 | 532508               | -                   |
| Etest® Ceftazidime/ceftazidime + clavulanic acid (4 µg/mL)               | TZ/TZL        | 0.5-32/0.064-4   | -                 | 532500               | -                   |
| Etest® Cefepime/cefepime + clavulanic acid (4 µg/mL)                     | PM/PMI        | 0.25-16/0.064-4  | -                 | 534708               | -                   |
| Etest® Cefepime/cefepime + clavulanic acid (4 µg/mL)                     | PM/PMI        | 0.25-16/0.064-4  | -                 | 534700               | -                   |
| <b>ETEST MBL for Detection of "Metallo Beta-lactamase"</b>               |               |                  |                   |                      |                     |
| Etest® Imipenem/imipenem + EDTA                                          | IP/IPI        | 4-256/1-64       | -                 | 534208               | -                   |
| Etest® Imipenem/imipenem + EDTA                                          | IP/IPI        | 4-256/1-64       | -                 | 534200               | -                   |
| Etest® Meropenem / Meropenem + EDTA                                      | MP/MPI        | 0.125-8/ 0.032-2 | -                 | 411361               | -                   |

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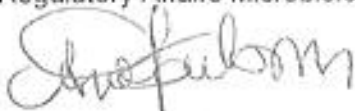
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**Name - Title / Nom - Fonction :**

Asa KARLSSON  
Sr. Manager, Regulatory Affairs Microbiology Unit

**Signature :**



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ETEST®

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Manuela KAUL

**Title / Fonction :**

VP Global Clinical & Regulatory Affairs

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**Manufacturer / Fabricant :**

**Name / Nom :**

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**Address / Adresse :**

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Directive 98/79/CE : ☐ List(e) A, Annex(e) II ☐ List(e) B, Annex(e) II ☒ Other / Autre ☐ Self-testing / Autotest



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|----------------------------------------------------|---------------------|------------------|--------------------------|----------------------------|----------------------------|
| <b>ETEST for Antibiotic Susceptibility Testing</b> |                     |                  |                          |                            |                            |
| Ettest® Amikacin                                   | AK                  | 0.016-256        | 501318                   | -                          | 412219                     |
| Ettest® Amoxicillin                                | AC                  | 0.016-256        | 500918                   | -                          | 412243                     |
| Ettest® Amoxicillin/clavulanic acid (2/1)          | XL                  | 0.016-256        | 501018                   | -                          | 412241                     |
| Ettest® Ampicillin                                 | AM                  | 0.016-256        | 501518                   | -                          | 412253                     |
| Ettest® Ampicillin/sulbactam (2/1)                 | AB                  | 0.016-256        | 501818                   | -                          | 412251                     |
| Ettest® Azithromycin                               | AZ                  | 0.016-256        | 501618                   | -                          | 412257                     |
| Ettest® Aztreonam                                  | AT                  | 0.016-256        | 501718                   | -                          | 412259                     |
| Ettest® Bacitracin                                 | BA                  | 0.016-256        | -                        | 528600                     | -                          |
| Ettest® Benzylpenicillin                           | PG                  | 0.016-256 (high) | 502518                   | -                          | 412263                     |
| Ettest® Benzylpenicillin                           | PG                  | 0.002-32 (low)   | 502618                   | -                          | 412265                     |
| Ettest® Cefaclor                                   | CF                  | 0.016-256        | -                        | -                          | 412271                     |
| Ettest® Cefepime                                   | PM                  | 0.016-256        | 505018                   | -                          | 412273                     |
| Ettest® Cefixime                                   | IX                  | 0.016-256        | 529918                   | -                          | 412275                     |
| Ettest® Cefoxime                                   | CT                  | 0.016-256 (high) | 505518                   | -                          | 412279                     |
| Ettest® Cefoxime                                   | CT                  | 0.002-32 (low)   | 505618                   | -                          | 412281                     |
| Ettest® Cefotetan                                  | DN                  | 0.016-256        | -                        | 505308                     | -                          |
| Ettest® Cefotetan                                  | DN                  | 0.016-256        | -                        | 506308                     | -                          |
| Ettest® Cefoxitin                                  | FX                  | 0.016-256        | 505518                   | -                          | 412285                     |
| Ettest® Cefprozil                                  | PK                  | 0.016-256        | 505818                   | -                          | 412289                     |
| Ettest® Cefprozil                                  | CPT                 | 0.002-32         | -                        | 517500                     | -                          |
| Ettest® Ceftriaxone                                | TZ                  | 0.016-256        | 506718                   | -                          | 412293                     |



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|-------------------------------------------|---------------------|-------------|--------|--------------------------|-----------------------------|----------------------------|
| Ettest® Ceftazidime/ Avibactam (4 µg/mL)  | CZA                 | 0.016 - 256 |        | -                        | -                           | 419556                     |
| Ettest® Ceftriaxone/ Tazobactam (4 µg/mL) | C/T                 | 0.016 - 256 |        | -                        | -                           | 414447                     |
| Ettest® Ceftriaxone                       | TK                  | 0.016-256   | (High) | 506618                   | -                           | 412101                     |
| Ettest® Ceftriaxone                       | TK                  | 0.002-32    | (Low)  | 507018                   | -                           | 412303                     |
| Ettest® Cefuroxime                        | RM                  | 0.016-256   |        | 506918                   | -                           | 412105                     |
| Ettest® Cephalothin                       | CE                  | 0.016-256   |        | -                        | -                           | 412507                     |
| Ettest® Chloramphenicol                   | CL                  | 0.016-256   |        | 507518                   | -                           | 412309                     |
| Ettest® Ciprofloxacin                     | CI                  | 0.002-32    |        | 506618                   | -                           | 412311                     |
| Ettest® Clarithromycin                    | CH                  | 0.016-256   |        | 508718                   | -                           | 412313                     |
| Ettest® Clindamycin                       | CM                  | 0.016-256   |        | 509518                   | -                           | 412315                     |
| Ettest® Colistin                          | CO                  | 0.016-256   |        | -                        | 517308                      | -                          |
| Ettest® Colistin                          | CO                  | 0.016-256   |        | -                        | 517300                      | -                          |
| Ettest® Daptomycin                        | DPC                 | 0.016-256   |        | 535018                   | -                           | 412324                     |
| Ettest® Doripenem                         | DOR                 | 0.002-32    |        | 535918                   | -                           | 412326                     |
| Ettest® Doxycycline                       | DC                  | 0.016-256   |        | 509718                   | -                           | 412328                     |
| Ettest® Enrofloxacin                      | EF                  | 0.002-32    |        | -                        | 528900                      | -                          |
| Ettest® Emazepam                          | ETP                 | 0.002-32    |        | -                        | -                           | 412332                     |
| Ettest® Emazepam                          | ETP                 | 0.002-32    |        | -                        | 531600                      | -                          |
| Ettest® Erythromycin                      | EM                  | 0.016-256   |        | 510518                   | -                           | 412334                     |
| Ettest® Fosfomycin                        | FM                  | 0.064-1024  |        | -                        | 529108                      | -                          |
| Ettest® Fosfomycin                        | FM                  | 0.064-1024  |        | -                        | 529100                      | -                          |
| Ettest® Fucidic acid                      | FU                  | 0.016-256   |        | -                        | 511508                      | -                          |
| Ettest® Fucidic acid                      | FU                  | 0.016-256   |        | 511510                   | -                           | -                          |
| Ettest® Gatifloxacin                      | GA                  | 0.002-32    |        | -                        | -                           | 412362                     |



DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

| PRODUCT NAME          | CODE ON STRIP | MIC (µg/mL) |        | FOAM PACK, REF NO. | BUSTER PACK, REF NO. | SINGLE PACK, REF NO. |
|-----------------------|---------------|-------------|--------|--------------------|----------------------|----------------------|
| Etest® Gentamicin     | GM            | 0.064-1024  | (high) | -                  | 512708               | -                    |
| Etest® Gentamicin     | GM            | 0.064-1024  | (high) | -                  | 512700               | -                    |
| Etest® Gentamicin     | GM            | 0.016-256   | (low)  | 512518             | -                    | 412368               |
| Etest® Imipenem       | IP            | 0.002-32    |        | 513618             | -                    | 412378               |
| Etest® Kanamycin      | KM            | 0.016-256   |        | 527818             | -                    | 412382               |
| Etest® Levofloxacin   | LE            | 0.002-32    |        | 527418             | -                    | 412388               |
| Etest® Linezolid      | LZ            | 0.016-256   |        | 531318             | -                    | 412396               |
| Etest® Meropenem      | MP            | 0.016-256   |        | -                  | 513700               | -                    |
| Etest® Meropenem      | MP            | 0.002-32    |        | -                  | 513808               | 412402               |
| Etest® Meropenem      | MP            | 0.002-32    |        | -                  | 513900               | -                    |
| Etest® Meropenem      | MP            | 0.016-256   |        | 530018             | -                    | 412404               |
| Etest® Meropenem      | MP            | 0.016-256   |        | 530018             | -                    | 412408               |
| Etest® Minocycline    | MX            | 0.002-32    |        | 529018             | -                    | 412412               |
| Etest® Moxifloxacin   | MU            | 0.064-1024  |        | -                  | 516308               | -                    |
| Etest® Mupirocin      | MU            | 0.064-1024  |        | -                  | 516300               | -                    |
| Etest® Nalidixic acid | NA            | 0.016-256   |        | -                  | 516508               | -                    |
| Etest® Nalidixic acid | NA            | 0.016-256   |        | -                  | 516500               | -                    |
| Etest® Nalidixic acid | NA            | 0.016-256   |        | 517518             | -                    | 412422               |
| Etest® Nitrofurantoin | NI            | 0.032-512   |        | -                  | 530408               | -                    |
| Etest® Nitrofurantoin | NI            | 0.032-512   |        | -                  | 530400               | -                    |
| Etest® Norfloxacin    | NX            | 0.016-256   |        | -                  | 519508               | -                    |
| Etest® Norfloxacin    | NX            | 0.016-256   |        | -                  | 519500               | -                    |
| Etest® Ofloxacin      | OF            | 0.002-32    |        | -                  | 519608               | -                    |
| Etest® Ofloxacin      | OF            | 0.002-32    |        | 519610             | -                    | -                    |



## DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

| PRODUCT NAME                                 | CODE ON STRIP | MIC (µg/mL)       | FOAM PACK REF NO. | BUSTER PACK REF NO. | SINGLE PACK REF NO. |
|----------------------------------------------|---------------|-------------------|-------------------|---------------------|---------------------|
| Etest® Oxacillin                             | OX            | 0.016-256         | 520518            | -                   | 412432              |
| Etest® Piperacillin                          | PP            | 0.016-256         | 521518            | -                   | 412436              |
| Etest® Polymyxin B                           | PB            | 0.064-1024        | -                 | 533408              | -                   |
| Etest® Polymyxin B                           | PB            | 0.064-1024        | -                 | 533400              | -                   |
| Etest® Quinupristin/dalfopristin             | QDA           | 0.002-32          | 528718            | 528708              | -                   |
| Etest® Quinupristin/dalfopristin             | QDA           | 0.002-32          | 528710            | 528700              | -                   |
| Etest® Rifampicin                            | R             | 0.002-32          | 526018            | -                   | 412450              |
| Etest® Spectinomycin                         | SC            | 0.064-1024        | 529218            | -                   | 412452              |
| Etest® Streptomycin                          | SM            | 0.064-1024        | -                 | 526808              | -                   |
| Etest® Streptomycin                          | SM            | 0.064-1024        | -                 | 526800              | -                   |
| Etest® Sulfamethoxazole                      | SA            | 0.064-1024        | 534118            | -                   | 412458              |
| Etest® Teicoplanin                           | TP            | 0.016-256         | 522018            | -                   | 412461              |
| Etest® Tetracycline                          | TC            | 0.016-256         | 522518            | -                   | 412471              |
| Etest® Ticarcillin/clavulanic acid (2 µg/ml) | TIC           | 0.016-256         | 522618            | -                   | 412473              |
| Etest® Tigecycline                           | TGC           | 0.016-256         | -                 | 533508              | 412475              |
| Etest® Tigecycline                           | TGC           | 0.016-256         | -                 | 533500              | -                   |
| Etest® Tobramycin                            | TM            | 0.064-1024 (high) | -                 | 533108              | -                   |
| Etest® Tobramycin                            | TM            | 0.064-1024 (high) | -                 | 533100              | -                   |
| Etest® Tobramycin                            | TM            | 0.016-256 (low)   | 532718            | -                   | 412479              |
| Etest® Trimethoprim                          | TR            | 0.002-32          | 523618            | -                   | 412483              |
| Etest® Trimethoprim/sulfamethoxazole (1/19)  | TS            | 0.002-32          | 524418            | -                   | 412481              |
| Etest® Vancomycin                            | VA            | 0.016-256         | 525518            | -                   | 412488              |



## DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

| PRODUCT NAME                                | CODE<br>ON<br>STRIP | MIC ( $\mu$ g/mL) | PDAM<br>PACK. REF.<br>NO. | BUSTER<br>PACK. REF.<br>NO. | SINGLE<br>PACK. REF.<br>NO. |
|---------------------------------------------|---------------------|-------------------|---------------------------|-----------------------------|-----------------------------|
| ETEST for Antifungal Susceptibility Testing |                     |                   |                           |                             |                             |
| Etect® Amphotericin B                       | AP                  | 0.002-32          | 526318                    | 526308                      | 412249                      |
| Etect® Amphotericin B                       | AP                  | 0.002-32          | -                         | 526300                      | -                           |
| Etect® Anidulafungin                        | AND                 | 0.002-32          | -                         | 532008                      | -                           |
| Etect® Anidulafungin                        | AND                 | 0.002-32          | -                         | 532000                      | -                           |
| Etect® Caspofungin                          | CS                  | 0.002-32          | 532418                    | -                           | 412289                      |
| Etect® Fluconazole                          | FL                  | 0.016-256         | 510818                    | -                           | 412950                      |
| Etect® Fluconazole                          | FC                  | 0.002-32          | 510918                    | -                           | 412952                      |
| Etect® Itraconazole                         | IT                  | 0.002-32          | 525818                    | -                           | 412380                      |
| Etect® Ketoconazole                         | KE                  | 0.002-32          | 525918                    | -                           | 412391                      |
| Etect® Micafungin                           | MVC                 | 0.002-32          | -                         | 515708                      | -                           |
| Etect® Micafungin                           | MYC                 | 0.002-32          | -                         | 535700                      | -                           |
| Etect® Posaconazole                         | POS                 | 0.002-32          | -                         | -                           | 412440                      |
| Etect® Posaconazole                         | POS                 | 0.002-32          | -                         | 532100                      | -                           |
| Etect® Voriconazole                         | VO                  | 0.002-32          | 532818                    | -                           | 412490                      |



## DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

| PRODUCT NAME                                                             | CODE ON STRIP | MIC (µg/ml)     | FOAM PACK, REF NO. | BUSTER PACK, REF NO. | SINGLE PACK, REF NO. |
|--------------------------------------------------------------------------|---------------|-----------------|--------------------|----------------------|----------------------|
| <b>ETEST ESBL for Confirmation of "Extended Spectrum Beta-Lactamase"</b> |               |                 |                    |                      |                      |
| Etect® Cefotaxime/cefotaxime + clavulanic acid (4 µg/ml)                 | CT/CTL        | 0.25-16/0.016-1 | -                  | 532208               | -                    |
| Etect® Cefotaxime/cefopime + clavulanic acid (4 µg/ml)                   | CT/CTL        | 0.25-16/0.016-1 | -                  | 532209               | -                    |
| Etect® Ceftazidime/ceftazidime + clavulanic acid (4 µg/ml)               | TZ/TZL        | 0.5-32/0.064-4  | -                  | 532508               | -                    |
| Etect® Ceftazidime/cefepime + clavulanic acid (4 µg/ml)                  | TZ/TZL        | 0.5-32/0.064-4  | -                  | 532509               | -                    |
| Etect® Cefepime/cefepime + clavulanic acid (4 µg/ml)                     | PM/PMI        | 0.25-16/0.064-4 | -                  | 534708               | -                    |
| Etect® Cefepime/cefepime + clavulanic acid (4 µg/ml)                     | PM/PMI        | 0.25-16/0.064-4 | -                  | 534709               | -                    |
| <b>ETEST MBL for Detection of "Metallo Beta-lactamase"</b>               |               |                 |                    |                      |                      |
| Etect® Imipenem/imipenem + EDTA                                          | IP/IPI        | 4-256/1-64      | -                  | 534208               | -                    |
| Etect® Imipenem/imipenem + EDTA                                          | IP/IPI        | 4-256/1-64      | -                  | 534209               | -                    |
| Etect® Meropenem / Meropenem + EDTA                                      | MP/MPI        | 0.125-8/0.032-2 | -                  | 411361               | -                    |