

Déclaration de  
conformité



Declaration of  
conformity

| Dispositif médical<br><i>Medical device</i>                                | Classe<br><i>Class</i> | Référence<br><i>Reference</i> |
|----------------------------------------------------------------------------|------------------------|-------------------------------|
| Cotyle <b>EMERGENCE</b> à cimenter<br><i>Cemented <b>EMERGENCE</b> cup</i> | III                    | H23 xx                        |

Nous, société EVOLUTIS, située à, Avenue de la libération 42720 Briennon, France

Déclarons que les dispositifs médicaux définis ci-dessus et détaillés dans l'addendum ci-joint (1 page) sont conformes aux Directives Européennes 93/42/CEE (annexe II – Section 4) 2005/50/CEE et 2007/47/CEE sur les dispositifs médicaux.

BSI (NL), organisme notifié N° 2797, a délivré le certificat **CE 644021**.

*We, EVOLUTIS company, located Avenue de la libération 42720 Briennon France*

*Hereby declare that the medical devices defined above and detailed in the enclosed addendum (1 page) are complying with the European Directive 93/42/EEC (appendix II – Section 4) 2005/50/EEC and 2007/47/EEC concerning medical devices.*

*BSI (NL), notified body N° 2797, issued certificate **CE 644021**.*

BRIENNON, le 27/08/2019

Date de validité : 26/05/2024

*Date of expiration*

Gérard PÉLISSON

Directeur Qualité / Affaires Règlementaires

*Quality and Regulatory Affairs Manager*

**E v o l u t i s**

C R E A T E U R F A B R I C A N T

Avenue de la libération - 42720 BRIENNON

Tél. : 04.77.60.79.99 Fax : 04.77.60.79.90

*Annexe à la déclaration de conformité  
 Declaration of conformity Addendum*

| Dispositif médical<br>Medical device                                | Classe<br>Class | Référence<br>Reference |
|---------------------------------------------------------------------|-----------------|------------------------|
| Cotyle <b>EMERGENCE</b> à cimenter<br>Cemented <b>EMERGENCE</b> cup | III             | H23 xx                 |

| Reference | Désignation 1 - FR             | Désignation 2 - FR         | Description 1 - UK        | Description 2 - UK      | Class |
|-----------|--------------------------------|----------------------------|---------------------------|-------------------------|-------|
| H23 E2242 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY diam 22.2-42 | EMERGENCE Cemented PE cup | CHARNLEY type Ø 22.2-42 | C3    |
| H23 E2244 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY diam 22.2-44 | EMERGENCE Cemented PE cup | CHARNLEY type Ø 22.2-44 | C3    |
| H23 E2246 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY Ø22.2-46     | EMERGENCE Cemented PE cup | CHARNLEY type Ø 22.2-46 | C3    |
| H23 E2248 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY Ø22.2-48     | EMERGENCE Cemented PE cup | CHARNLEY type Ø 22.2-48 | C3    |
| H23 E2250 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY Ø22.2-50     | EMERGENCE Cemented PE cup | CHARNLEY type Ø 22.2-50 | C3    |
| H23 E2252 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY Ø22.2-52     | EMERGENCE Cemented PE cup | CHARNLEY type Ø 22.2-52 | C3    |
| H23 E2254 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY Ø22.2-54     | EMERGENCE Cemented PE cup | CHARNLEY type Ø 22.2-54 | C3    |
| H23 E2256 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY Ø22.2-56     | EMERGENCE Cemented PE cup | CHARNLEY type Ø 22.2-56 | C3    |
| H23 E2258 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY Ø22.2-58     | EMERGENCE Cemented PE cup | CHARNLEY type Ø 22.2-58 | C3    |
| H23 E2844 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY diam 28-44   | EMERGENCE Cemented PE cup | CHARNLEY type Ø 28-44   | C3    |
| H23 E2846 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY diam 28-46   | EMERGENCE Cemented PE cup | CHARNLEY type Ø 28-46   | C3    |
| H23 E2848 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY diam 28-48   | EMERGENCE Cemented PE cup | CHARNLEY type Ø 28-48   | C3    |
| H23 E2850 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY diam 28-50   | EMERGENCE Cemented PE cup | CHARNLEY type Ø 28-50   | C3    |
| H23 E2852 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY diam 28-52   | EMERGENCE Cemented PE cup | CHARNLEY type Ø 28-52   | C3    |
| H23 E2854 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY diam 28-54   | EMERGENCE Cemented PE cup | CHARNLEY type Ø 28-54   | C3    |
| H23 E2856 | Cotyle PE EMERGENCE à cimenter | Type CHARNLEY D28-56       | EMERGENCE Cemented PE cup | CHARNLEY type Ø 28-56   | C3    |
| H23 E2858 | Cotyle PE EMERGENCE à cimenter | type CHARNLEY diam 28-58   | EMERGENCE Cemented PE cup | CHARNLEY type Ø 28-58   | C3    |