SOP 4.2.1.1 Form 1 Rev 4.0

Declaration of Conformity

1. Manufacturer: Oystershell NV, Nijverheidsweg 10, 9820 Merelbeke, Belgium, declares this EU declaration of conformity is issued under his sole responsibility.

1. The product with Basic UDI-DI [5410765ExcilorForteQ4] and Formula Reference [X92001650]:

Device name	Package	Ref. number	Risk class / rule[1]
Excilor Forte®	Bottle - 30 ml	62040006	IIa/ rule 4, par. 3

2. Described above is in conformity with the Directive:

Document No.	Title	Edition / Date of issue
DIR 93/42/EEC	Medical Device Directive	Current version

2. Additional information (conformity procedure, Notified Body, CE certificate, etc.):
   Conformity assessment procedure for CE marking: Council Directive 93/42/EEC, Annex II excl chapter 4.

   This declaration is made on the basis of the quality assurance certificate n°**: BE19/819943435** (CE certificate number) delivered by Notified Body **n° 1639:** SGS Belgium NV, SGS House Noorderlaan 87, 2030 Antwerp, Belgium.

28 October 2020, Merelbeke:

Bart Rossel*

Chief Scientific Officer

Oystershell NV

*Representing Pepperstreet Capital BV

[1] See risk classification in Medical Device Directive, Annex IX