

DECLARATION OF CONFORMITY

Manufacturer Name : Tabib Farma İlaç Tıbbi Cihazlar Medikal Ortopedi Gıda Tarım Bitkisel Yağlar Üretimi İnşaat Ve İnşaat Malzemeleri Sanayi Ve Ticaret Ltd. Şti.

Adres: Sanayi Mah. 3327 Sk. Gülpetek Sanayi Sitesi S Ada 3 Blok No:3 Merkez Isparta
TÜRKİYE

We declare that the product mentioned below is in compliance with (2007/47 EC medical device directives) (include Article 4) medical device directives

Product Name : GENTA ANTIBIOTICS BONE CEMENT
Brand : ALCASIS™
Product Information : 41 gram
Ref No : 291453/41G
Class : III
Rule : 13
GMDN Code : 35217 (Cement, Orthopedic, Bone) Disposable, Implantable and non-active

EN ISO 15223-1: 2016, TS EN 1041+A1:2014, EN ISO 11135:2014, EN ISO 13408-1:2015, EN 556-1:2001, EN 556-2:2015, TS EN ISO 11737-1/AC:2010, TS EN ISO 11737-2 :2010, EN ISO 10993-1:2011, EN ISO 10993-1 /AC:2014, EN ISO 10993-3:2015, EN ISO 10993-5:2010, EN ISO 10993-6:2017, EN ISO 10993-07:2010, EN ISO 10993-10:2014, EN ISO 10993-11:2010, EN ISO 14971:2013, TS EN ISO 14971/D1 :2016, TS EN ISO 14698-1:2004, TS EN ISO 13485:2016, TS EN ISO 14644-1:2016, TS EN ISO 14644-2:2016, TS EN ISO 14644-3:2016, TS EN ISO 14630:2013, TS EN ISO 11607-1/A1:2014, TS EN ISO 11607-2/A1:2014, TS ISO 5833:2014, MEDDEV 2.7.1:4, MEDDEV 2.12.1:8, MEDDEV 2.12.2:2, NBOG 2010-1:2010

Approving Establishment: UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi
Sanayi ve Ticaret Limited Şirketi 2073 Sokak No:10, Ümitköy/Ankara, 06810
Çankaya/Ankara
EC Certificate No: M.2020.106.13928
EC and Design Certificate Date: 05.10.2020
Design Certificate No: M.2020.106.13928-1
Approving Establishment's No: 2292

This declaration applies to all CE marked products unless it's cancellation or issuance of another declaration

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General Manager
Yavuz GENÇ