



EC DECLARATION of CONFORMITY

MANUFACTURER : Tules Medikal Sanayi ve Ticaret A.Ş.
MANUFACTURER ADDRESS : Fatih Mahallesi 1213 Sokak No.8/A Gaziemir/İZMİR
PHONE : 0232 332 11 51
FAX : 0232 332 11 51
E-MAIL : info@tulesmedikal.com.tr
PRODUCT BRAND : TULES
PRODUCT NAME : Non-Sterile Vomit Bag with Drawstring Absorbent Pad
MODEL / REF. NO : TLS-002
BARCODE : 8682257402022
CLASSIFICATION : Class I Other (non-sterile product with no measuring function)
GMDN CODE : 36258 (Emesis bag)
INTENDED USE : A disposable, single-use, nonsterile device intended to collect and contain a patient's vomit until it is convenient to dispose of it and its contents to prevent possible contamination in hospital environment, in operation/surgery room or intensive care units. This is a single-use device. Provides patient comfort by capturing smell with absorbent pad inside the plastic bag.
CONFORMITY :



Our company manufactures the products declared above in accordance with the requirements of the existing TS EN ISO 15223-1, TS EN ISO 10993-1, TS EN 1041+A1, TS EN ISO 14971 and ISO 13845:2016 Medical Devices Quality Management System. The products defined above were subjected to initial type tests by the manufacturer, and factory production Control was carried out by making regular tests. The continuity of the tests is provided by the manufacturer.

PLACE of ISSUE : İzmir / TURKEY
DATE of ISSUE : 26/10/2021
AUTHORIZED PERSON : Meral KUPİK
AUTHORIZED TITLE : General Manager
APPROVAL (STAMP & SIGNATURE) :

TULES MEDİKAL
SANAYİ VE TİCARET A.Ş.
Fatih Mah.1213 Sok. No:8/A Gaziemir/İZMİR
Gaziemir V.D:861 0788 182 Tic. Sic. No:204259
Mersis No:0861 0788 1820 0001