

BSCIC

Certíficate

MEDICAL DEVICE-QUALITY MANAGEMENT SYSTEM

This is to certify that:

THARMAC GmbH

IM DACHSSTÜCK 15, 65549, LIMBURG AN DER LAHN, HESSEN, GERMANY

Hereby granted the Certificate Number:

BN23169/21838

Rev. 00

Subsequent to the **Assessment** of the organization, it has been found to be operating a Medical Device-Quality Management System which complies with the requirements of

ISO 13485:2016

For the following scope:

Primary Label Manufacturing and Distributing GynoPrep (Fixation Fluid), Centrifuges and its Accessories for IVD.

Technical area: Distribution Services (Distributors providing Storage and Delivery of Medical Devices, not acting as a 'legal manufacturer' for Medical Devices.), A.1.7.5

