Manufacturer's Declaration of Conformity

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

Full Quality Assurance Procedures

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian ***Therapeutic Goods (Medical Devices) Regulations 2002*** relating to the stated devices

Manufacturer's Name: Waters Corporation
Business Address: 34 Maple Street,
Milford, MA 01757
USA

IVD Medical Devices:
MassTrak™ Steroid Serum Cal Set 1: 186009311IVD
MassTrak™ Steroid Serum QC Set 1: 186009312IVD
MassTrak™ Endocrine Blank Calibrator: 186010560IVD
MassTrak™ Steroid Serum Cal Set 2: 186010563IVD
MassTrak™ Steroid Serum QC Set 2: 186010564IVD
MassTrak™ Steroid Serum Cal Set 3: 186010565IVD
MassTrak™ Steroid Serum QC Set 3: 186010566IVD
MassTrak™ Steroid Internal Standard Mix: 186010567IVD
MassTrak™ Steroid Optimization Mix: 186010568IVD

Classification: Class 2 IVD

GMDN Code and Term: CT850, Clinical Chemistry Hormone IVDs

Scope of Application: All

Each kind of IVD medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable classification rules and essential principles, at each stage from the design of the device until its final inspection before being supplied.

This declaration is being made on the basis of the following certificate:

Full Quality Management System Certificate: ISO 13485:2016 & EN ISO 13485:2016 certificate number:
MD 742044, issued by BSI Group The Netherlands B.V.

Conformity Assessment Standards Applied: EN ISO 13485:2016

Authorised Signatory:

DocuSigned by:
Colleen Adams
Signer Name: Colleen Adams
Signing Reason: I approve this document
Signing Time: 15-Feb-2024 | 10:33 EST
30F8F0B4E677450BA10A3A416BA9EABB

K. Colleen Adams, MTSC
Senior Director, Regulatory & Clinical Affairs, Waters Corporation

15-Feb-2024 | 10:33 EST

Date
Issued: Milford, MA, USA