
Declaration of Conformity

MANUFACTURER: Shanghai Chemtron Biotech. CO., LTD
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PRODUCT: Name: One-Step PSA Test
Type: Cassette

CLASSIFICATION: List B

CONFORMITY ASSESSMENT ROUTE: Annex IV

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PREDUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN ISO 13485: 2012/AC:2012
EN ISO 18113-1: 2011
EN ISO 18113-2: 2011
EN ISO 15223-1:2012
EN 13612: 2002
EN 13640: 2002
EN 13641: 2002
EN ISO 14971: 2012
EN ISO 17511: 2003

NOTIFIED BODY: Name: TÜV SÜD Product Service GmbH
Address: Ridlerstraße 65

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SIGNATURE:



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