# DECLARATION OF CONFORMITY

| | | | |
|---|---|---|---|
| **Date of issue** | Not applicable | **Valid until** | Not applicable |
| **CE Assessment certificate** | This product has been assessed on conformity according to the essential requirements as listed in Annex I of the European Directive 98/79/EC on in vitro diagnostic medical devices (IVDD). Certification by a Notified Body is not required. | | |
| **Certificate no.** | Not applicable | | |

| | | | |
|---|---|---|---|
| **Product code** | IQP-396 | **Product name** | HIT*Alert*™ Kit |
| **EDMA code** | 130204.90 | **EDMA term** | Other Primary Hemostasis/Platelet Factors |
| **EMDN code Level 4** | W010302 | **EMDN term** | Haemostasis Reagents (Coagulation) |
| **GMDN code** | 61512 | **GMDN term** | Platelet factor 4-heparin complex total antibody IVD, kit, agglutination, rapid |
| **Basic UDI - DI** | 87179530223IQP-396NX | | |
| **Intended use** | Immune heparin induced thrombocytopenia (HIT) is a distinct syndrome in which laboratory detection of the pathological HIT antibodies is diagnostically useful. The HIT*Alert*™ Kit, a qualitative, rapid, non-automated and flow cytometric platelet activation assay, which detects antibodies based on their characteristic platelet-activating properties in venous blood samples of patients suspected of HIT. This HIT*Alert*™ Kit should be used as a screening test and only be executed and interpreted by well-trained and authorized laboratory technicians. The results should always be used in conjunction with clinical findings and other serological tests. | | |

| | |
|---|---|
| **Manufacturer name and Address** | IQ Products BV,<br>Rozenburglaan 13a,<br>9727 DL Groningen, The Netherlands |
| **Single Registration number (SRN)** | NL-MF-000010812 |
| **Competent Authority** | Dutch Health Care Inspectorate CIBG,<br>registration no. NL-CA002-24457 |
| **Harmonized Standards Referenced** | • EN ISO 13485:2016<br>• EN 13641:2002<br>• EN 13612:2002<br>• EN 13975:2003<br>• EN ISO 14971:2012<br>• EN ISO 18113-1:2011<br>• EN ISO 18113-2:2011<br>• EN ISO 23640:2015<br>• EN ISO 15223-1:2021 |
| **Other regulations/standards by which the product is regulated** | Regulation (EC) No. 1272/2008;<br>Regulation (EU) No. 453/2010;<br>Regulation (EU) No. 2015/830. |

This declaration of conformity is issued under the sole responsibility of IQ Products BV.

(1) The product meet the provisions of the Directive 98/79/EC on in vitro diagnostic medical devices which apply to the products;

(2) The HIT*Alert*™ kit is placed on the market for the first time in 2012;

(3) The product concerned is produced at the manufacturing facility of IQ Products B.V. in conformance with the design control procedure requirements as specified in Directive 98/79/EC and the records are available for review;

(4) The product comply with all essential requirements of the Directive 98/79/EC on in vitro diagnostic medical devices;

(5) IQ Products BV has a Quality System in place based on ISO 13485:2016. The Quality System has been certified and the certificate has been issued by Notified Body DEKRA Certification B.V. (Identification number 0344) on February 01, 2022 and expires on February 01, 2025;

We hereby certify that as of the date of this declaration, the product described above conform with the provisions of the European Directive 98/79/EC on in vitro diagnostic medical devices (IVDD). All supporting documentation is retained at IQ Products BV.

This declaration of conformity is issued under the sole responsibility of IQ Products BV

Date: _____ Signature: _____

Place: Groningen, the Netherlands

Name: Christine M. Kebbedies

Function: Manager QA & RA

Company: IQ Products BV