Conformity to Type based on Quality Assurance of the Production Process

This is to certify that:

TIDI Products LLC
570 Enterprise Drive
Neenah
Wisconsin
54956
USA

Holds Certificate Number: CE 716567

In respect of:

X-Ray protective clothing and eyewear

on the basis that BSI carried out the quality assurance assessment under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VIII (Module D)

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086

First Issued: 2019-10-15

Effective Date: 2019-10-15

Latest Issue: 2019-10-15

Expiry Date: 2024-10-15

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No. CE 716567

Design location:
TIDI Products LLC
570 Enterprise Drive
Neenah
Wisconsin 54956
USA

Production Location:
Domico Med-Device LLC
14241 Fenton Road
Fenton
MI 48430
USA

Product Specification

The products covered by the scope of this Certificate conform to the following standards:

Standard	Product Type
Technical Specification	To Annex II of Regulation (EU) 2016/425 for X-ray protective garments and eyeshields
EN 61331-3:2014	Diagnostic x-ray protection devices - Part 3: Protective clothing and gonads
EN 166:2001	Personal eye-protection — Specifications

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Certificate Administration Details

Certificate Administration Record and BSI internal Technical File Review reference

Issue date	Comments	BSI Project Ref.
October 2019	First issue	2797:19:3064811

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes

The validity of the Certificate is also dependent on the maintenance of a documented quality system

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