

## Declaration

**PRODUCT:** WONDERLITE® PC-115P  
**DATE OF DECLARATION:** 2024/01/01  
**DATE OF EXPIRATION:** 2025/12/31

To the best of our current knowledge, we hereby certify that the above final resin product(s) solely and directly supplied by us to you, comply with following statement.

- Follow Medical Device Regulation(MDR) EC 1272/2008, above product don't contain substances which list in table 3 annex VI of regulation EC1272/2008 in a concentration that is above 0.1 % weight by weight (w/w)
- Comply with ISO-10993 Biocompatibility Study of Medical Device Services.

### **In Vitro**

- ISO-10993-5 *In Vitro Cytotoxicity Test*
- ISO-10993-4 *Partial Thromboplastin Time (PTT) Test*
- ISO-10993-4 *Platelet Counting Test*
- ISO-10993-3 *Salmonella Reverse Mutation Test*
- ISO-10993-3 *In Vitro Mammalian Cell Gene Mutation Test*

### **In Vivo**

- ISO-10993-10 *Skin Sensitization Study (Maximization Test)*
- ISO-10993-10 *Intracutaneous Reactivity Test*
- ISO-10993-11 *Acute Systemic Toxicity Study*
- ISO-10993-6 *Muscle Implant Study*
- ISO-10993-11 *Repeat-Dose Subchronic Systemic Toxicity Study*

The above statement is based on our current level of knowledge and covers the above products directly manufactured and supplied by CHI MEI CORPORATION at the date of issue. CHI MEI CORPORATION makes no warranties, whether express or implied, and assumes no liability in connection with any use of above information. Notwithstanding the foregoing, CHI MEI CORPORATION shall in no event be held obligated or liable for any claims due to or arising from (i) any customer provided, consigned, materials and/or parts, which are incorporated or adopted in the products; (ii) any combination of the products with material not provided or authorized by our company; (iii) any modifications to the products which are made or directed by customer; (iv) our compliance with the specifications, instructions, and/or designs provided by customer; (v) any anti-trust, unfair competition and/or other unlawful actions effected by customer; or (vi) any defects, infringement, breach and/or violation which are arising out of customer's faults or otherwise not solely and directly attributable to CHI MEI CORPORATION. In no event will CHI MEI CORPORATION be liable for any indirect, special, exemplary, punitive, or consequential damages (including lost profits) of any nature whatsoever whether arising out of the purchase, shipment, unloading, handling, or use of any product or otherwise.

- Comply with USP88 Class VI Biological Reactivity of Materials.
  - ***Intracutaneous Irritation*** Study in White Rabbits
  - ***Acute Systemic Toxicity*** Study in Mice
  - ***Muscle Implantation*** Study in White Rabbits for 7 Days

Sincerely Yours,

Product Programming Department

The above statement is based on our current level of knowledge and covers the above products directly manufactured and supplied by CHI MEI CORPORATION at the date of issue. CHI MEI CORPORATION makes no warranties, whether express or implied, and assumes no liability in connection with any use of above information. Notwithstanding the foregoing, CHI MEI CORPORATION shall in no event be held obligated or liable for any claims due to or arising from (i) any customer provided, consigned, materials and/or parts, which are incorporated or adopted in the products; (ii) any combination of the products with material not provided or authorized by our company; (iii) any modifications to the products which are made or directed by customer; (iv) our compliance with the specifications, instructions, and/or designs provided by customer; (v) any anti-trust, unfair competition and/or other unlawful actions effected by customer; or (vi) any defects, infringement, breach and/or violation which are arising out of customer's faults or otherwise not solely and directly attributable to CHI MEI CORPORATION. In no event will CHI MEI CORPORATION be liable for any indirect, special, exemplary, punitive, or consequential damages (including lost profits) of any nature whatsoever whether arising out of the purchase, shipment, unloading, handling, or use of any product or otherwise.