

Certificate CN15/10580

The management system of

Shandong Pharmaceutical Glass Co., Ltd.



No. 1 Yaobo Road, Yiyuan County, Zibo City, Shandong Province, P.R. China

has been assessed and certified as meeting the requirements of

ISO 15378:2017

Primary packaging materials for medicinal products – Particular requirements for the application of ISO9001:2015 with reference to Good Manufacturing Practices (GMP)

For the following activities

Design and manufacture of halogenated butyl rubber stoppers for pharmaceutical industry

Manufacture of tubular pharmaceutical glass vials made of low borosilicate glass and neutral borosilicate glass

Design and manufacture of moulded pharmaceutical glass vials made of neutral borosilicate glass and soda-lime glass

Manufacture of assemblages for prefilled syringes (with stainless steel needles and without stainless steel needles)

The responsibility for the quality of the individual batches of the primary packaging materials for medicinal products manufactured, packed and stored lies with the organization

This certificate is valid from 15 October 2024 until 14 October 2027 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 15 October 2015

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by

Ben Tsang

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Certificate CN15/10580, continued

Shandong Pharmaceutical Glass Co., Ltd.

SGS

ISO 15378:2017

Primary packaging materials for medicinal products – Particular requirements for the application of ISO9001:2015 with reference to Good Manufacturing Practices (GMP)

Issue 6

Sites

Shandong Pharmaceutical Glass Co., Ltd.

No. 1 Yaobo Road, Yiyuan County, Zibo City, Shandong Province, P.R. China

Design and manufacture of moulded pharmaceutical glass vials made of neutral borosilicate glass

Top management, Administration and Human Resource, Financial Dept., Sales Dept., Quality Management Dept., Safety and Production Dept., Purchasing Dept., Material Management Dept.

Shandong Pharmaceutical Glass Co., Ltd.

Yiyuan County Economic Development Zone, Zibo City, Shandong Province, P.R. China

Design and manufacture of halogenated butyl rubber stoppers for pharmaceutical industry

Manufacture of tubular pharmaceutical glass vials made of low borosilicate glass and neutral borosilicate glass

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