

## **Statement regarding compliance with California Health & Safety Code § 119402**

Pursuant to California Health & Safety Code, Sections 119400 – 119402, (“California Compliance Law”), which requires the adoption of a comprehensive compliance program in accordance with the Office of Inspector General (“OIG”) for the United States Department of Health and Human Services April 2003 publication “Compliance Program Guidance for Pharmaceutical Manufacturers” (“OIG Compliance Program Guidance”).

Dutch Ophthalmic, USA, Inc. (“Dutch USA”) has established a Healthcare Compliance Program in accordance with the OIG Compliance Program Guidance and has policies in place to foster compliance with government and applicable industry code requirements and expectations. Consistent with the requirements of the California Compliance Law and as part of the Healthcare Compliance Program, Dutch USA has established a specific annual aggregate dollar limit of USD \$2,000 on gifts, promotional materials, or items or activities that Dutch USA may give or otherwise provide to an individual medical or health professional in California on an annual basis from January 1 to December 31. The \$2,000 limit does not include the value of items expressly excluded by California law, including product samples given to physicians and other healthcare professionals intended for free distribution to patients.

The items and activities covered by the law and Dutch USA policy are primarily directed to the dissemination or communication of medical and scientific information as a resource for health professionals to assist in making clinical or other medical judgments. This limit may be revised from time to time, in which case the revised limit will be published in this section of the Dutch USA website. This limit represents a spending maximum, and the amount spent per medical or health professional may be significantly less than the maximum amount. Dutch USA has established an internal monitoring system designed to help ensure compliance with the annual spending limit in California as well as other spending limits across the United States.

## **Annual Declaration (July 2023)**

Dutch USA is committed to conducting business activities in compliance with applicable laws, rules and regulations, and following the highest ethical standards in its interactions with all medical and health professionals and organizations. It is the policy of Dutch USA that all interactions with medical and health professionals and organizations that are made on behalf of Dutch USA are consistent with ethical business practices and socially-responsible industry conduct. Dutch USA’s Healthcare Compliance Program and related policies and procedures are an expression of this core value, and are intended to provide guidelines for complying with the law for all Dutch USA personnel and agents.

To the best of its knowledge and based on a good faith understanding of the statutory requirements, Dutch USA has established a Healthcare Compliance Program that meets the requirements set forth in California Health & Safety Code, Sections 119400-119402. Dutch USA has tailored its Healthcare Compliance Program to meet the specific needs of Dutch USA and continuously assesses the effectiveness of the



Healthcare Compliance Program. Our company has established an internal monitoring system designed to help ensure compliance with its respective annual spending limits in California and other similar spend limits across the United States. Therefore, subject to the limitations described above, Dutch USA declares that, based upon current tracking and monitoring systems, Dutch USA is materially in compliance with its Healthcare Compliance Program and applicable law, including the established annual spending limits in California for the period of January 1, 2022, through December 31, 2022.

For a written copy of Dutch USA's Healthcare Compliance Program description or this declaration, please call (908) 309-1454.

To report compliance questions or potential compliance concerns, Dutch USA encourages you to contact our Compliance email address at [compliance@dorcglobal.com](mailto:compliance@dorcglobal.com).