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The Provisions of Medical Device Nomenclature

（Exposure Draft）

Article 1

The provisions are formulated in accordance with the Regulations on the Supervision and Administration of Medical Devices, with a view to strengthen the supervision and management of medical device and guarantee the medical device nomenclature is scientific and normative.

Article 2

All the medical device nomenclature what activities in the distribution and usage within the territory of the People's Republic of China shall comply with the administrative measures.

Article 3

Generic name of medical device shall comply with relevant national laws and regulations, and consistence with actual attribute of the product. It must be scientific, specific, and cannot mislead and deceive user.

Article 4

Generic name of medical device shall use Chinese language, and comply with the norms of the standard spoken and written Chinese language of State.

Article 5

Medical devices shall use the same generic name in the same variety. Generic name is formed by a chest word and no more than three feature words in general.

Article 6

Chest word is the most general statement of medical devices which with the same or similar technical principle, structure composition, performance index and intended use.

Article 7

Feature word refers to the description about usage area, structure feature, technical feature,

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material composition, specific attribute and so on of medical device.

Usage area refers to the acting object or acting point of main function. It can be human body, tissues, structures, whole or partial organs.

Structure feature refers to the description about specific structure and appearance of medical device.

Technical feature refers to the explanation or limitation about special action principle or action mechanism of medical device.

Material composition refers to the description about main material of medical device.

Specific attribute refers to the definitive description about special performance.

Article 8

Generic name of medical device shall not contain the following:

1. Model or specifications
2. Signs about symbol, graph and so on
3. Person name, corporation name, brand name or other similar name.
4. The absolute or exclusive terms about “the best”, “the latest”, “the sole”, “the accurate”, “quick acting” and so on.
5. Express or imply that the medical device has therapeutic effects on disease, or assertions or assurances in terms to effectiveness, efficient and cure rates,
6. Express or imply that the medical device can cure all diseases and indications, or exaggerate contents of indication, or publicity about “hairdressing”, “health care” and so on.
7. The content without scientific proven or clinically proven, or conceptual name with nothingness and assumption.
8. Other content prohibited by relevant laws and regulations;

Article 9

Generic name of medical device shall not be registered as trademark.

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Article 10

Generic name of in vitro diagnosis reagent shall be named according relevant regulation about in vitro diagnostic reagents.

Article 11

These provisions shall put in force from XXX

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