



September 16, 2015

TILLER MIND BODY INC.
JERI TILLER
10911 WEST AVENUE
SAN ANTONIO TX 78213

Re: Description: HEALTH CARE PLUMBING APPLIANCE
Manufacturer: TILLER MIND BODY INC.
Product Name: LIBBE COLONIC DEVICE (trans id 2565380)
Model Number(s): 9703
Product File No: 20150174

The specifications and/or plans for this plumbing product have been reviewed and determined to be in compliance with chapters SPS 382 through 384, Wisconsin Administrative Code, and Chapters 145 and 160, Wisconsin Statutes.

The Department hereby issues an approval based on the Wisconsin Statutes and the Wisconsin Administrative Code. This approval is valid until the end of September 2020.

This approval is contingent upon compliance with the following stipulation(s):

- This device shall be installed by a properly licensed Wisconsin plumber.
- This device is a United States Food and Drug Administration (USFDA) registered "Class II" medical device under CFR Title 21, Chapter 1, Subchapter H, Part 876, Subpart F, Section 876.5220.

A Class II medical device, by definition, may only be used when medically indicated (e.g. radiological or endoscopic examinations). A Class II medical device **IS NOT** intended for other uses, including colon cleansing routinely for general well-being.

Therefore, users of this device must first obtain a written prescription from a properly licensed Wisconsin healthcare provider. In addition, Federal law restricts this device to sale by, or on the order of, a physician or licensed healthcare provider.

- Any medical professional/therapist using this device on a patient must first have successfully completed device training from Tiller MIND BODY, Inc.
- Only single use, disposable, speculums/nozzles shall be used.
- All pressure vacuum breakers shall:
 1. Conform to ASSE Standard 1056;
 2. be installed in accordance with SPS 382.41 (5) Wis. Adm. Code;
 3. be registered in accordance with SPS 382.20 (13) Wis. Adm. Code; and
 4. be tested in accordance with SPS 382.21 (8) Wis. Adm. Code.
- The wastewater from these devices shall be discharged to a properly sized sanitary drain, waste and vent (DWV) system and conform to SPS 382.33 (9) (a) 2. and SPS 382.382.10 (1) (f) Wis. Adm. Code. Existing DWV piping must be large enough to handle the additional wastewater load generated by this device.

Tiller Mind Body Incorporated
September 16, 2015
Page 2 of 2
Product File No. 20150174

- This device is approved for use with unadulterated (i.e. no additives) water only.

The department is in no way endorsing this product or any advertising, and is not responsible for any situation which may result from its use.

Sincerely,

Glen W. Schlueter
Environmental Engineer - Plumbing Product Reviewer
Dept of Safety and Professional Services
Division of Industry Services
Bureau of Technical Services
(608) 267-1401 Phone
(608) 267-9723 Fax
glen.schlueter@wi.gov E-mail