

**HOUSE . . . . . No. 3274**

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**The Commonwealth of Massachusetts**

PRESENTED BY:

***Peter J. Durant***

*To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:*

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to repairs made to medical devices.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Peter J. Durant</i>	<i>6th Worcester</i>	<i>1/16/2015</i>
<i>Brian M. Ashe</i>	<i>2nd Hampden</i>	<i>3/23/2015</i>
<i>Shaunna L. O'Connell</i>	<i>3rd Bristol</i>	<i>3/22/2015</i>

**HOUSE . . . . . No. 3274**

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By Mr. Durant of Spencer, a petition (accompanied by bill, House, No. 3274) of Peter J. Durant, Brian M. Ashe and Shaunna L. O’Connell relative to repairs made to medical devices. Public Health.

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**The Commonwealth of Massachusetts**

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**In the One Hundred and Eighty-Ninth General Court  
(2015-2016)**  
\_\_\_\_\_

An Act relative to repairs made to medical devices.

*Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:*

1 Chapter 111N of the General Laws is hereby amended by adding the following section:-

2 Section 9. SECTION 2. Said chapter 111, as appearing in the 2012 Official Edition, is  
3 hereby amended by inserting after section 31E the following section:-

4 Section 31F. (a) As used in this section the following words shall, unless the context  
5 clearly requires otherwise, have the following meanings:—

6 “FDA standards for medical device manufacturers”, regulations promulgated by the Food  
7 and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act for the  
8 manufacture of medical devices including those regulations set forth in 21 C.F.R. Parts 800 to  
9 1299, inclusive.

10           “License”, a valid and current certificate of qualification issued by the department which  
11 shall medical device repair companies authority to engage in the repair of medical devices in the  
12 commonwealth.

13           “Licensee”, a medical device repair company holding a license issued by the department  
14 pursuant to this section.

15           “Medical device repair corporation”, a corporation, LLC or partnership engaged in the  
16 practice of repairing medical devices in the commonwealth.

17           (b) No medical device repair corporation shall repair medical devices or engage in the  
18 practice of repairing medical devices in the commonwealth unless issued a license pursuant to  
19 this section. Licenses issued under this section shall be granted to corporations meeting the  
20 criteria for qualification as established by this section and the department.

21           (c) License certificates bearing the licensee's name, license number, and the calendar year  
22 in which the license is valid shall be issued to all qualified licensees.

23           (d) All licensees shall abide by all federal, state, and local laws and ordinances. No  
24 license issued by the department may be sold or transferred.

25           (e) Every licensee shall notify the department of the address of the name and address of  
26 business. Licensees shall give immediate notice to the department of any change in this  
27 information. Service of any process shall be achieved by mailing notice of such information by  
28 first class postage, U.S. Postal Service, to the address of record. No further service of process  
29 shall be required.

30 (f) All applicants for licenses or license renewals shall be required to complete specific  
31 application forms developed and provided by the department.

32 (g) All required fees and documentation shall accompany any application form filed with  
33 the department.

34 (h) The department shall approve the issuing of a license to each applicant meeting the  
35 qualifications as set forth by the department, or deny a license to each applicant not meeting the  
36 qualifications as set forth by the department.

37 (i) The department shall develop eligibility requirements to be met by applicants seeking  
38 licensing by the department. The minimum application requirements shall include, but are not  
39 limited to, the applicant's ability to satisfy the FDA standards for medical device manufacturers.

40 (j) The department shall maintain an official list of licensees and publish the list on its  
41 website.

42 (k) A license is only valid during the calendar year indicated on the license. At the end of  
43 that calendar year, the license will expire unless it is renewed by the licensee. All licensees shall  
44 make application for license renewal at least 30 days prior to the expiration of a current license.

45 (l) License renewal application forms and license renewal requirements shall be  
46 developed by the department.

47 (m) Failure to meet renewal requirements shall result in expiration and revocation of a  
48 license. Upon expiration of a license, the licensee's name shall be removed from the department's  
49 official list.

50 (n) The department shall establish criteria for circumstances warranting the suspension or  
51 revocation of a license and establish the procedures for suspension or revocation of licenses.  
52 These circumstances shall include, but not be limited to, failure to conform with the FDA  
53 standards for medical device manufacturers and failure to follow the rules and regulations of the  
54 department.

55 The department shall take appropriate action to enforce the rules adopted with regard to  
56 license suspension or revocation. After suspension or revocation of a license, the department  
57 shall publish this information to the public.

58 (o) Whoever repairs or attempts to repair a medical device without first having obtained  
59 and having possession of a current, valid license from the department or who knowingly presents  
60 or files false information with the department for the purpose of obtaining a license or otherwise  
61 fraudulently obtains a license, or who knowingly violates any provision of this section shall be  
62 punished by imprisonment in the house of correction for not more than 2½ years or by a fine of  
63 not more than \$20,000 or by both.