



METRO HEALTH

UNIVERSITY OF MICHIGAN HEALTH

November 15, 2019

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

**Re: License No. 21-12829-01, Metro Health University of Michigan Health
Confirmation of proctored SIR-Sphere procedures**

Dear Madam or Sir:

Enclosed please find documentation that Matthew A. Tiede, M.D. as had completed three SIR-Sphere procedures under the physical presence of the manufacturer's representative.

If you have any questions regarding this matter, please contact Dawn Edwards, at 734-662-3197 or dedwards@mpcphysics.com or Suzanne Kasper, at 616-252-7355 or Suzanne.kasper@metrogr.org.

Sincerely,

Suzanne Kasper
Radiology Operations Manager

RECEIVED NOV 19 2019



SIRTEX MEDICAL INC.

300 Unicorn Park Drive

Woburn, MA 01801

Tel: +1 (781) 721 3800

Fax: +1 (781) 721 3880

Ref: 105US03

November 12, 2019

Dr. Matthew Tiede
Metro Health Hospital
5900 Byron Center Avenue SW
Wyoming, MI 49519

Dear Dr. Tiede;

Re: SIR-Spheres® Yttrium-90 Resin Microspheres Training, Evaluation, Certification (TEC) Program

I am writing to confirm that on October 23, 2019, Dr. Doug Coldwell presented and discussed the preparation of and procedures associated with SIR-Spheres yttrium-90 (Y-90) resin microspheres that are injected via the hepatic artery to treat patients with unresectable liver tumors. I am pleased to inform you that Sirtex considers that you and your staff are trained in the preparation and clinical aspects of treating patients with SIR-Spheres Y-90 resin microspheres.

This letter also certifies that you were proctored by a Sirtex certified proctor in the use of SIR-Spheres Y-90 resin microspheres on the following dates: April 23, 2019 (dose administration); May 21, 2019 (dose administration); and October 23, 2019 (dose administration).

I would like to thank you and your team for your support and commitment to the Sirtex **Training, Evaluation, Certification (TEC) Program**.

Yours sincerely,

William T. Denman, MD
Global Chief Medical Officer

cc: Justin Rickard, Regional Sales Manager
TEC@sirtex.com

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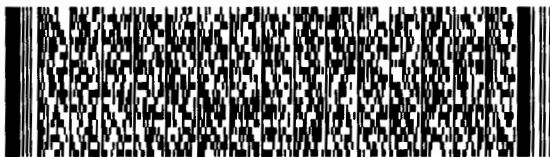
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