CLAIMS:

1. An irradiation device for insertion into an orifice of the body for providing photodynamic therapy or diagnosis, the device comprising: a housing adapted to be fully inserted and secured in the orifice, the housing enclosing an LED lamp system and a power source for powering the LED lamp system; and the housing comprising a treatment surface, with the LED lamp system being arranged to, when the device is in operation, emit light from the treatment surface; wherein the treatment surface is at least partially transparent to said light and has a size and/or shape adapted for complementary fit with a treatment area within the orifice such that, when the device is in operation, the treatment area is illuminated by said light; and wherein the device is independently operational while located in the orifice.

2. A device as claimed in claim 1 wherein the housing further comprises a flexible outer portion which can, in use, adjust its shape to form a secure fit with the walls of the orifice.

3. A device as claimed in claim 2 wherein the flexible outer portion forms a continuous surface which tapers outwards towards the rear of the device.

4. A device as claimed in claim 2 or 3 wherein the flexible outer portion is formed of a resilient material.

5. A device as claimed in claims 2 to 4 wherein the flexible outer portion is formed of silicone.

6. A device as claimed in any preceding claim wherein the entire housing is flexible.

7. A device as claimed in any preceding claim wherein the treatment surface is at least partially transparent to light having wavelengths emitted by the LED lamp system.

8. A device as claimed in any preceding claim, wherein the treatment surface is formed by a surface of a portion of the housing material, and the material is arranged to diffuse the light emitted from the LED lamp system.

9. A device as claimed in any preceding claim wherein a transparent material is used to form both the housing around the LED lamp system and the treatment surface, and the material is acting as a diffuser for the light emitted from said LED lamp system.

10. A device as claimed in any preceding claim, comprising a switch for activation of the lamp system.

11. A device as claimed in claim 10, wherein the switch is enclosed within the housing and is arranged to be operated whilst sealed within the housing.

12. A device as claimed in any preceding claim wherein the LED lamp system is arranged to provide, in use, a light intensity in the range of 1 – 50 mW/cm^2.

13. A device as claimed in claim 12 wherein the LED lamp system is arranged to provide, in use, a light intensity in the range of 1 to 10 mW/cm^2.

14. A device as claimed in any preceding claim wherein the at least one LED emits light having wavelengths in the range of 300-800 nm, preferably in the range of 630-690 nm.

15. A device as claimed in any preceding claim, the LED lamp system comprising a control circuit for regulating the irradiation provided by the at least one LED.

16. A device as claimed in claim 15, wherein the control circuit is a control circuit that is programmed to provide pulsed illumination.

17. A device as claimed in claim 15 or 16, wherein the control circuit comprises a receiver for connection to a remote terminal and/or a feedback system and/or one or more performance indicator lights for informing a user whether the device has operated correctly.

18. A device as claimed in any preceding claim wherein the device further comprises a lens system arranged to provide homogenous illumination over the treatment area.

19. A device as claimed in claim 18 when dependent upon any preceding claim wherein the treatment surface comprises the lens system.

20. A device as claimed in any preceding claim, further comprising a drug carrying area for carrying a composition comprising a photosensitizer or precursor of a photosensitizer.

21. A device as claimed in claim 20 wherein said drug carrying area is the treatment surface.

22. A device as claimed in claim 21 wherein the composition comprises5-ALA or a derivative of 5-ALA or a pharmaceutically acceptable salt thereof.

23. A device as claimed in claim 22, wherein the composition comprises a 5-ALA ester or a pharmaceutically acceptable salt thereof.

24. A device as claimed in claim 23, wherein the 5-ALA ester is a compound of formula (I) or a pharmaceutically acceptable salt thereof:

$R^2{}_2N\text{-}CH_2COH_2\text{-}CH_2CO\text{-}OR^1$

wherein
R^1 is straight chain C_1-C_6 alkyl and both R^2 represent hydrogen.

25. A device as claimed in claims 20 to 24 wherein said composition is a semi-solid or solid composition.

26. A device as claimed in claims 20 to 25 which is provided separately from the composition.

27. A device as claimed in claims 20 to 25 which is provided with the composition contained in said drug carrying area.

28. A device as claimed in any preceding claim, wherein the device includes one or more features that promote single-use and/or prevent repeat use.

29. A device as claimed in claim 28, wherein the power source is arranged to provide power that is only sufficient for a single-use and/or the control circuit is arranged to prevent re-use by means of features of its programming and/or the control circuit includes a deactivation mechanism that destroys circuitry or software when triggered.

30. An irradiation device for insertion into an orifice of the body for providing photodynamic therapy or diagnosis, the device comprising: a housing adapted to be inserted and secured in the orifice, the housing enclosing an LED lamp system and a power source for powering the LED lamp system, and the housing comprising a treatment surface with the LED system being arranged to emit radiation from the treatment surface; wherein the device is independently operational while located in the orifice, characterised in that the housing comprises a flexible outer portion that can, in use, adjust its shape to form a secure fit within the

walls of the orifice, the outer portion extending away from the treatment surface towards the rear of the device and tapering outwards such that the widest section of the outer portion is located rearwards of the treatment surface, whereby the housing is adapted to be fully inserted and secured in the orifice.

31. An irradiation device as claimed in claim 30 further comprising a drug carrying area for carrying a composition comprising a pharmaceutically acceptable salt of 5-ALA hexyl ester.

32. An irradiation device as claimed in claim 31 wherein said composition is a semi-solid composition.

33. An irradiation device as claimed in claim 32 wherein said device is provided separately from the composition.

34. An irradiation device for insertion into an orifice of the body for providing photodynamic therapy, the device comprising: a housing adapted to be fully inserted and secured in the orifice, the housing enclosing an LED lamp system and a power source for powering the LED lamp system and the housing comprising a treatment surface with the LED system being arranged to, when the device is in operation, emit light at a light intensity in the range of 1-50 mW/cm^2 form the treatment surface, wherein the treatment surface is at least partially transparent to said light and has a size and/or shape adapted for complementary fit with a treatment area within the orifice such that, when the device is in operation, the treatment area is illuminated by said light and wherein the device is independently operational while located in the orifice.

35. An irradiation device as claimed in any preceding claim for use in a method of photodynamic treatment of a treatment area within an orifice of the body, the method comprising applying a composition comprising a photosensitizer or precursor of a photosensitizer to the treatment area and inserting an irradiation device as claimed in the preceding claims into the orifice, such that the LED lamp system of the irradiation device operates to provide illumination to the treatment area.

36. An irradiation device as claimed in any of claims 1 to 34 for use in a method as claimed in claim 35 wherein the composition is supplied via a drug carrying area comprised on the device such that the steps of application of the composition and insertion of the device occur simultaneously.

37. An irradiation device as claimed in any of claims 1 to 34 for use in a method as claimed in claims 35 and 36 wherein the LED lamp system of the irradiation device provides a light dose of 10 to 200 J/cm^2.

38. An irradiation device as claimed in any of claims 1 to 34 for use in a method as claimed in claim 37 wherein the LED lamp system of the irradiation device is arranged to provide, in operation, a fluence rate in the range of 1 to 10 mW/cm^2.

39. An irradiation device as claimed in any of claims 1 to 33 for use in a method as claimed in claims 35 to 38 for the treatment of the vagina or the cervix.

40. An irradiation device as claimed in claim 39 for the treatment of cervical cancer and cervical diseases, lesions or conditions.

41. An irradiation device as claimed in claim 40 wherein those cancer, diseases, lesions and conditions, are caused by HPV infection.

42. A kit comprising the irradiation device as claimed in claims 1 to 34 and at least one composition comprising a photosensitizer or precursor of a photosensitizer for use with the device.

CLAIMS:

1. An irradiation device for insertion into an orifice of the body for providing photodynamic therapy or diagnosis, the device comprising: a housing adapted to be fully inserted and secured in the orifice, the housing enclosing an LED lamp system and a power source for powering the LED lamp system; and the housing comprising a treatment surface, with the LED lamp system being arranged to, when the device is in operation, emit light from the treatment surface; wherein the treatment surface is at least partially transparent to said light and has a size and/or shape adapted for complementary fit with a treatment area within the orifice such that, when the device is in operation, the treatment area is illuminated by said light; and wherein the device is independently operational while located in the orifice.

2. A device as claimed in claim 1 wherein the housing further comprises a flexible outer portion which can, in use, adjust its shape to form a secure fit with the walls of the orifice.

3. A device as claimed in claim 2 wherein the flexible outer portion forms a continuous surface which tapers outwards towards the rear of the device.

4. A device as claimed in claim 2 or 3 wherein the flexible outer portion is formed of a resilient material.

5. A device as claimed in claims 2 to 4 wherein the flexible outer portion is formed of silicone.

6. A device as claimed in any preceding claim wherein the entire housing is flexible.

7. A device as claimed in any preceding claim wherein the treatment surface is at least partially transparent to light having wavelengths emitted by the LED lamp system.

8. A device as claimed in any preceding claim, wherein the treatment surface is formed by a surface of a portion of the housing material, and the material is arranged to diffuse the light emitted from the LED lamp system.

9. A device as claimed in any preceding claim wherein a transparent material is used to form both the housing around the LED lamp system and the treatment surface, and the material is acting as a diffuser for the light emitted from said LED lamp system.

10. A device as claimed in any preceding claim, comprising a switch for activation of the lamp system.

11. A device as claimed in claim 10, wherein the switch is enclosed within the housing and is arranged to be operated whilst sealed within the housing.

12. A device as claimed in any preceding claim wherein the LED lamp system is arranged to provide, in use, a light intensity in the range of 1 – 50 mW/cm^2.

13. A device as claimed in claim 12 wherein the LED lamp system is arranged to provide, in use, a light intensity in the range of 1 to 10 mW/cm^2.

14. A device as claimed in any preceding claim wherein the at least one LED emits light having wavelengths in the range of 300-800 nm, preferably in the range of 630-690 nm.

15. A device as claimed in any preceding claim, the LED lamp system comprising a control circuit for regulating the irradiation provided by the at least one LED.

16. A device as claimed in claim 15, wherein the control circuit is a control circuit that is programmed to provide pulsed illumination.

17. A device as claimed in claim 15 or 16, wherein the control circuit comprises a receiver for connection to a remote terminal and/or a feedback system and/or one or more performance indicator lights for informing a user whether the device has operated correctly.

18. A device as claimed in any preceding claim wherein the device further comprises a lens system arranged to provide homogenous illumination over the treatment area.

19. A device as claimed in claim 18 when dependent upon any preceding claim wherein the treatment surface comprises the lens system.

20. A device as claimed in any preceding claim, further comprising a drug carrying area for carrying a composition comprising a photosensitizer or precursor of a photosensitizer.

21. A device as claimed in claim 20 wherein said drug carrying area is the treatment surface.

22. A device as claimed in claim 21 wherein the composition comprises5-ALA or a derivative of 5-ALA or a pharmaceutically acceptable salt thereof.

23. A device as claimed in claim 22, wherein the composition comprises a 5-ALA ester or a pharmaceutically acceptable salt thereof.

24. A device as claimed in claim 23, wherein the 5-ALA ester is a compound of formula (I) or a pharmaceutically acceptable salt thereof:

$R^2{}_2N\text{-}CH_2COH_2\text{-}CH_2CO\text{-}OR^1$

wherein
R^1 is straight chain C_1-C_6 alkyl and both R^2 represent hydrogen.

25. A device as claimed in claims 20 to 24 wherein said composition is a semi-solid or solid composition.

26. A device as claimed in claims 20 to 25 which is provided separately from the composition.

27. A device as claimed in claims 20 to 25 which is provided with the composition contained in said drug carrying area.

28. A device as claimed in any preceding claim, wherein the device includes one or more features that promote single-use and/or prevent repeat use.

29. A device as claimed in claim 28, wherein the power source is arranged to provide power that is only sufficient for a single-use and/or the control circuit is arranged to prevent re-use by means of features of its programming and/or the control circuit includes a deactivation mechanism that destroys circuitry or software when triggered.

30. An irradiation device for insertion into an orifice of the body for providing photodynamic therapy or diagnosis, the device comprising: a housing adapted to be inserted and secured in the orifice, the housing enclosing an LED lamp system and a power source for powering the LED lamp system, and the housing comprising a treatment surface with the LED system being arranged to emit radiation from the treatment surface; wherein the device is independently operational while located in the orifice, characterised in that the housing comprises a flexible outer portion that can, in use, adjust its shape to form a secure fit within the

walls of the orifice, the outer portion extending away from the treatment surface towards the rear of the device and tapering outwards such that the widest section of the outer portion is located rearwards of the treatment surface, whereby the housing is adapted to be fully inserted and secured in the orifice.

31. An irradiation device as claimed in claim 30 further comprising a drug carrying area for carrying a composition comprising a pharmaceutically acceptable salt of 5-ALA hexyl ester.

32. An irradiation device as claimed in claim 31 wherein said composition is a semi-solid composition.

33. An irradiation device as claimed in claim 32 wherein said device is provided separately from the composition.

34. An irradiation device for insertion into an orifice of the body for providing photodynamic therapy, the device comprising: a housing adapted to be fully inserted and secured in the orifice, the housing enclosing an LED lamp system and a power source for powering the LED lamp system and the housing comprising a treatment surface with the LED system being arranged to, when the device is in operation, emit light at a light intensity in the range of 1-50 mW/cm^2 form the treatment surface, wherein the treatment surface is at least partially transparent to said light and has a size and/or shape adapted for complementary fit with a treatment area within the orifice such that, when the device is in operation, the treatment area is illuminated by said light and wherein the device is independently operational while located in the orifice.

35. An irradiation device as claimed in any preceding claim for use in a method of photodynamic treatment of a treatment area within an orifice of the body, the method comprising applying a composition comprising a photosensitizer or precursor of a photosensitizer to the treatment area and inserting an irradiation device as claimed in the preceding claims into the orifice, such that the LED lamp system of the irradiation device operates to provide illumination to the treatment area.

36. An irradiation device as claimed in any of claims 1 to 34 for use in a method as claimed in claim 35 wherein the composition is supplied via a drug carrying area comprised on the device such that the steps of application of the composition and insertion of the device occur simultaneously.

37. An irradiation device as claimed in any of claims 1 to 34 for use in a method as claimed in claims 35 and 36 wherein the LED lamp system of the irradiation device provides a light dose of 10 to 200 J/cm^2.

38. An irradiation device as claimed in any of claims 1 to 34 for use in a method as claimed in claim 37 wherein the LED lamp system of the irradiation device is arranged to provide, in operation, a fluence rate in the range of 1 to 10 mW/cm^2.

39. An irradiation device as claimed in any of claims 1 to 33 for use in a method as claimed in claims 35 to 38 for the treatment of the vagina or the cervix.

40. An irradiation device as claimed in claim 39 for the treatment of cervical cancer and cervical diseases, lesions or conditions.

41. An irradiation device as claimed in claim 40 wherein those cancer, diseases, lesions and conditions, are caused by HPV infection.

42. A kit comprising the irradiation device as claimed in claims 1 to 34 and at least one composition comprising a photosensitizer or precursor of a photosensitizer for use with the device.

43. A composition comprising 5-ALA or a derivative of 5-ALA or a pharmaceutically acceptable salt thereof, the composition being for use in a method for photodynamic therapy of a treatment area within the female reproductive tract or the rectum by means of the device or kit of any preceding claim, the method comprising: administration of the composition; insertion of the device into the body such that the treatment surface is in complementary fit with the treatment area; and illuminating the treatment area with light from the LED lamp system of the device.

44. A composition as claimed in claim 43 comprising a 5-ALA ester or a pharmaceutically acceptable salt thereof, preferably a 5-ALA ester which is a compound of formula (I) or a pharmaceutically acceptable salt thereof:

$R^2{}_2N\text{-}CH_2COH_2\text{-}CH_2CO\text{-}OR^1$

wherein

R^1 is straight chain C_1-C_6 alkyl and both R^2 represent hydrogen.

45. A composition as claimed in claim 43 comprising 5-ALA hexyl ester or a pharmaceutically acceptable salt thereof.

46. A composition as claimed in any of claims 43 to 45 wherein said composition is a semi-solid or solid composition.

47. A composition as claimed in any of claims 43 to 46 being for use in a method for photodynamic therapy of the vagina or cervix.

48. A composition as claimed in claim 47 being for use in a method for photodynamic therapy of cervical cancer and cervical diseases, lesions or conditions.